DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

PHARMACY RULES AND REGULATIONS

3 CCR 719-1

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

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.

1.00.24 A prescription drug outlet shall ensure that all prescription drugs and controlled substances are procured from another entity or person registered by the Colorado State Board of Pharmacy. Any drug designated as an Investigational New Drug from the Federal Food and Drug Administration is exempt from this requirement provided the research requirements for the receipt of the product are followed and it meets the requirements of CRS 12-22-128(2). *[Eff. 11/30/2008]*

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 for hospitalized patients (hospital chart orders): *[Eff. 11/30/2008]*

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

b. In the case of a prescription or chart order for a resident of a long term care facility (LTCF chart order), the assigned serial number.

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

d. 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 or LTCF chart order when appropriate:

a. Any change in or clarification of an order shall be documented on the order and shall bear 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 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 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 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 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 for a hospitalized patient (hospital chart order), the following information need <u>not</u> 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, license number, or secure electronic identifier 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 database 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 and the original quantity prescribed 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 11.04.10.

2.01.55 The receiving prescription drug outlet shall retain the transferred prescription order as required by Regulation 11.04.10.

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

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, that 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.

2.01.80 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 11.04.20 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) 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) 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.

3.00.21 A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized

practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should have known that the order for such drug was issued on the basis of an internet-based questionnaire, an internet-based consultation, or a telephonic consultation, all without a valid preexisting patient-practitioner relationship.

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 Initial Interpretation and Final Evaluation. *[Eff. 11/30/2008]*

a. Initial interpretation means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/manual transcription and for drug regimen review.

b. Final evaluation means the review of the final prescription to ensure that the ordered medication is properly prepared and placed in a suitable container with appropriate labeling. The pharmacist(s) conducting the final evaluation shall be held accountable for assuring that the identity of the drug that appears on the prescription label corresponds with identity of drug contained therein. When refills are dispensed, the pharmacist conducting the final evaluation shall be held accountable for the appropriate dispensing of refills including all drug utilization reviews as they pertain to refill dispensing.

c. Drug regimen review includes but is not limited to the evaluation of order(s) and patient records(s) for:

1) Known allergies;

2) Rational therapy and contraindications;

3) Reasonable dose, duration of use, and route of administration considering age, gender, and other patient factors;

4) Reasonable directions for use;

5) Potential or actual adverse drug reactions;

6) Drug-drug interactions;

7) Drug-food interactions;

8) Drug-disease contraindications;

9) Therapeutic duplication;

10) Proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and

11) Abuse/misuse.

d. A pharmacist shall conduct an initial interpretation of each new order and a pharmacist shall conduct the final evaluation of each order dispensed. When refills are dispensed, the

pharmacist making the final evaluation shall be held accountable for the appropriate dispensing of refills. The pharmacist manager shall be held accountable for the maintenance of all appropriate records.

e. The original prescription or LTCF order shall bear the identity of the pharmacist making the initial interpretation, by either license number, initials, name or secure electronic identifier. The pharmacist making the initial interpretation on a hospital chart order shall be identified as required by regulation 2.01.20(c). The pharmacist making the final evaluation shall be identified by either license number, initials, name, or secure electronic identifier on a uniformly maintained, readily retrievable document. The order or a uniformly maintained, readily retrievable document shall bear the license number, initials, name, or secure electronic identifier of any additional pharmacists involved in the dispensing of the order. The pharmacist conducting the initial interpretation and final evaluation may be the same person.

f. In the case where the computer software utilized is not password protected, the initial interpretation and final evaluation shall be maintained in a handwritten format bearing the license number, initials, or name of the responsible pharmacist. In addition, the identification of any other pharmacists involved in the dispensing shall be maintained in the same handwritten format.

3.00.51 Records of Initial Interpretation and Final Evaluation. *[Eff. 11/30/2008]*

a. Records detailing both the initial interpretation and final evaluation shall be retained at the prescription drug outlet for each prescription dispensed and for at least two years from the date of any transaction pertaining to the order. These records shall include at least the following:

1. The license number, initials, name, or secure electronic identifier of the pharmacist conducting the initial interpretation for each new order;

2. The license number, initials, name, or secure electronic identifier of the pharmacist conducting the final evaluation for each new and refill prescription; and

3. The specific date on which each initial interpretation and final evaluation occurred. In the event the initial interpretation and final evaluation for a new order are conducted on separate dates, both dates shall be recorded to state specifically when both occurred.

b. Each outlet shall maintain, in written format, a notice detailing how initial interpretations and final evaluations are documented in the outlet. Such notice shall include and comply with the following:

1. The manner in which initial interpretations are recorded and maintained in the outlet for all new orders.

2. The manner in which final evaluations are recorded in the outlet for all new and refill prescriptions.

3. A statement that all pharmacy personnel involved in the dispensing of prescriptions have the ability to print, upon request, a record detailing the initial interpretation for each new prescription dispensed and final evaluation for each new and refill prescription dispensed.

4. Such written notice shall be signed and dated by the pharmacist manager. In the

event the pharmacist manager changes, the incoming pharmacist manager shall review, sign and date the notice within 72 hours of assuming the duties of pharmacist manager. In the event there is a lapse between the time one pharmacist manager ceases the duty and another assumes the duty, the previous method of recording initial interpretations and final evaluations shall remain in effect.

5. If there are any changes to the outlet's method of documenting initial interpretations and final evaluations, a new written notice detailing the requirements of sections 1., 2., 3. And 4 above shall be executed. This notice shall detail the effective date of change.

6. The outlet shall post these notices on a wall directly next to the outlet's most current board registration.

7. These notices shall be retained at the outlet for a period of three years from the date last utilized.

8. In the event such notices are not posted, the pharmacist manager shall be held accountable for the failure to post the required notice and any dispensing errors. In the event such notices are not posted during the period of time between one pharmacist manager leaving the position and another assuming the position, the outlet shall be held accountable for the failure to post the required notice and any dispensing errors.

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 or Donation. No prescription drug outlet shall accept drugs for return or exchange for redispensing or donation after such drugs have been dispensed except in the following situations:

a. An outlet that complies with Regulations 3.00.81 through 3.00.85 may accept drugs for return and redispensing. Such prescription drug outlet shall have return drug protocols approved by the Board.

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 and the following requirements are met:

(1) An appropriate, uniformly maintained and readily retrievable record shall be maintained which indicates at least the total number of doses of the drug which were actually administered. This record may be combined with the record

permitted by regulation 2.01.20(c); or

(2) If the drug was distributed as floor stock in the facility, an appropriate, uniformly maintained and readily retrievable record of such return shall be made. This record shall state the following:

(a) The name of the drug;

(b) The strength of the drug;

(c) The dosage form of the drug if appropriate;

(d) The quantity of the drug;

(e) The location within the facility to which the drug was originally distributed; and

(f) The date of the return.

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

d. Any medication returned for redispensing or donation from an inpatient hospice, nursing care facility, or assisted living residence that is licensed pursuant to section CRS 25-3-101 shall bear an expiration date that is at least six months after the date the drug was returned.

e. In an inpatient hospice, nursing care facility, or assisted living residence that is licensed pursuant to section 25-3-101, C.R.S., a patient, resident, or the patient's or resident's next of kin may return unused medication to the prescription drug outlet which had originally dispensed the medication. The prescription drug outlet may redispense the medication to another patient of the same facility from which it was returned or it may donate the medication to a non-profit entity that has the legal authority to possess the medication. Such donation and redispensing shall comply with all requirements of regulations 3.00.80 through 3.00.85. For the purposes of this regulation, a non-profit entity that has legal authority to possess the medication is defined as a registered other outlet which is non-profit, or a registered prescription drug outlet which is non-profit.

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. "Customized patient medication package" means a package which contains two or more drugs.

g. “Automated cassette” is a container that is filled with a drug. This container may count the drug and may package the drug into a container suitable for dispensing, and may affix a label to the container. These cassettes may be used to dispense drugs in a traditional dispensing system or may be used to package unit-dose medication, or drugs in a unit of issue packaging system. An automated cassette shall not be used for schedule II controlled substances.

h. “Package” means to prepare a drug in a container other than the original container. The packaging might include a unit dose dispensing system, single dose, automated cassette, or a container suitable for a traditional system. Unless otherwise specified, this includes preparing a drug in advance of the immediate need for dispensing (prior to the receipt of an order), or pursuant to an existing order.

3.00.82 No prescription drug outlet shall accept a returned drug product for redispensing or donation 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, redispensing, and donation, 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 packaging with a description of the container system(s), labeling and records to be kept, including examples and/or samples as appropriate.

c. Records of receipt of returned drugs shall include at least the following:

(1) Date of return to the pharmacy;

(2) Date dispensed;

(3) Prescription number;

(4) Drug name and strength;

(5) Quantity returned; and

(6) Expiration date of drug.

d. Records of donation to non-profit entities with authority to possess drugs shall include at least the following:

(1) Name and address of non-profit entity;

(2) Name and strength of drug;

(3) The dosage form, if appropriate;

(4) The quantity of drug;

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

generic name;

(6) The date of distribution;

(7) The name and address of the distributing pharmacy; and

(8) Expiration date of drug.

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

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 packaged into unit dose or unit of issue packages in the prescription drug outlet may be redispensed one time only, except as provided for in 3.00.80(b), provided that the integrity of the product and the package are maintained.

c. Drug products which have been packaged 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 packaged, nor may additional units of medication be added to partially-used unit of issue packages.

d. Drug products which have been packaged 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 packaged.

e. Drug products which have been packaged into unit of issue packages or single dose packages may be removed from such packages and packaged 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 or LTCF chart order but has not been delivered to the ultimate consumer, the drug may be returned to stock for subsequent redispensing provided that:

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

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

(1) Prescription number;

(2) Drug name and strength;

(3) Quantity returned to stock;

(4) Date of return; and

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

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

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

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

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

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

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

3.01.00 Packaging.

3.01.10

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

approved by the Board.

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

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

3.01.20 Each packaged container, whether for use in a unit dose distribution system or a traditional dispensing system, shall be labeled in accordance with this regulation. Any packaged unit dose, single dose or unit of issue container for which return for restocking and redispensing, pursuant to 3.00.80, is anticipated, shall be labeled in accordance with this regulation. Additionally, any packaged container from which subsequent dispensing may occur, shall be labeled in accordance with this regulation. Such labeling shall include at least the following: *[Eff. 11/30/2008]*

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

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

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

d. The identity of the manufacturer or distributor;

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

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

g. The date the product was packaged;

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

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

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

3.01.22 Filling of automated cassettes.

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

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

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

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

2. Name and strength of the medication;

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

4. The identity of the manufacturer or distributor;

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

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

7. The date the product was packaged;

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

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

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

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

3.01.23 Maintenance of automated cassette records.

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

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

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

3.01.24 Electronic Maintenance of Packaging Records.

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

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

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

c. The prescription drug outlet must:

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

or

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

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

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

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

(3) It is the responsibility of the prescription drug outlet manager to ensure that all prescription drug outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the prescription drug outlet manager and/or a

staff pharmacist to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these regulations.

e. Whether the prescription drug outlet elects to comply with regulation 3.01.24(d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:

1. Name and strength of the medication;

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

3. The identity of the manufacturer or distributor;

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

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

6. The date the product was packaged;

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

3.01.25 Maintenance and cleaning of automated cassettes

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

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

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

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

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

3.03.00 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 Pharmacopoeia standards.

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

3.03.20 It shall not be considered redispensing for a prescription drug outlet to modify a customized medication package which it has previously dispensed if the following criteria are met:

a. The med pak is modified for the same patient for which it was originally dispensed.

b. The med pak is returned to the prescription drug outlet from which it was originally dispensed.

c. Only discontinued medication may be removed from the med pak. Additional medications may not be added.

d. The medications removed from the med pak are destroyed. They may not be redispensed.

d. The med pak is assigned a new serial number.

e. The labeling of the med pak is modified to comply with 3.03.10(a). The expiration date affixed to the label prior to modification must be retained.

f. Records are maintained for the modified med pak which comply with regulation 3.03.10(b).

3.04.00 Colorado Cancer Drug Repository Program.

3.04.10 A prescription drug outlet may accept donations of non-controlled cancer drugs and medical devices (prescription drugs and devices that are used to treat cancer or the side effects of cancer) from cancer patients or the cancer patient's family, provided the drugs or devices meet the following requirements:

a. The drug or device is in the original, unopened, sealed, and tamper-evident unit-dose packaging, or if in a single unit dose package, the single unit dose package is unopened;

b. The drug or device is not expired;

c. The drug or device is not adulterated or misbranded as determined by the pharmacist;

d. The drug or device does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and

e. The drug or device does not require patient registration with the drug manufacturer prior to dispensing.

3.04.20 The drugs and devices shall be stored in the compounding/dispensing area under manufacturer's recommended storage conditions. The drugs and devices shall be stored separately from the other drug stock. *[Eff 10/01/2006]*

3.04.30 Dispensing/distribution of repository drugs/devices. *[Eff 10/01/2006]*

3.04.31 The prescription drug outlet may distribute the donated drugs or devices to the following: *[Eff 10/01/2006]*

a. A medical clinic, which is defined as a community health clinic required to be licensed or certified by the Colorado Department of Public Heath and Environment. Such clinic must be registered with the board as an other outlet; or *[Eff 10/01/2006]*

b. A registered prescription drug outlet. *[Eff 10/01/2006]*

3.04.32 The prescription drug outlet may dispense the drugs or devices to eligible patients based on a valid order from a practitioner. The prescription drug outlet shall establish criteria for individuals to receive donated cancer drugs or devices. The pharmacy may only charge a handling fee for such dispensing. This fee shall be determined by the State Board of Health.

3.04.40 Recordkeeping. *[Eff 10/01/2006]*

3.04.41 The prescription drug outlet shall retain separate records detailing the receipt and distribution/dispensing of repository drugs and devices. *[Eff 10/01/2006]*

3.04.42 Records of receipt shall include at least the following:

a. Name and address of person donating the drug or device;

b. Drug or device name and strength;

c. Manufacturer of drug or device;

d. Manufacturer's lot number;

e. Drug or device expiration date, if Applicable;

f. Date received; and

g. Quantity received.

3.04.43 Records or distribution shall include at least the following:

a. Name and address of medical clinic or prescription drug outlet;

b. Drug or device name;

c. Drug strength;

d. Dosage form, if appropriate;

e. Quantity distributed;

f. Identity of manufacturer of drug or device;

g. Manufacturer's lot number;

h. Drug or device expiration date, if applicable;

i. Date of distribution; and

j. Name and address of distributing pharmacy.

3.04.44 Records of dispensing shall include at least the following; *[Eff 10/01/2006]*

a. Patient name; *[Eff 10/01/2006]*

b. Prescription number; *[Eff 10/01/2006]*

c. Drug or device name and drug strength; *[Eff 10/01/2006]*

d. Quantity dispensed; *[Eff 10/01/2006]*

e. Practitioner's name; *[Eff 10/01/2006]*

f. Date dispensed; *[Eff 10/01/2006]*

g. Identity of drug or device manufacturer; and *[Eff 10/01/2006]*

h. Drug or device lot number. *[Eff 10/01/2006]*

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) These hours may be obtained by participation in a rotation program conducted by an accredited school or college of pharmacy; and/or internship hours may be independently obtained by a licensed intern enrolled in, in good standing with, or having 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 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.

c. 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.

d. 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.

e. 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.

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 or rule.

c. A preceptor who meets the requirements of these rules and who has been 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 oversee 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. More than one pharmacist or other authorized person may be approved by the Board as a preceptor at any location.

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. Applicants for license transfer must have been licensed for at least one year or have served an Internship meeting the Colorado requirements at the time of original licensure.

e. 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. Examination scores are valid for 24 months from the date of 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.

h. Intern hours obtained over five years past graduation from a school or college of pharmacy shall not be valid for the purposes of obtaining a license by examination or score transfer.

4.03.00 Reinstatement or Reactivation of Pharmacist License.

a. If the license has been inactive or expired for over 24 months, a person wishing to reinstate or reactivate such license shall do the following:

(1) Submit the appropriate application with the required fee;

(2) Submit 1 hour of continuing education for each month such license was inactive or expired. Twenty-four (24) of these hours shall have been completed in the 24 months prior to application for reinstatement or reactivation; and

(3) Take and pass the approved jurisprudence examination. The passing point shall be set at 75 to reflect minimum competency.

b. If the license has been expired or inactive for less than 24 months, a person wishing to reinstate or reactivate such license shall do the following:

(1) Submit the appropriate application with the required fee; and

(2) Submit 24 hours of continuing education completed within the 24 months prior to application.

4.04.00 Repealed.

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 and interns 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.

5.00.01 Definitions. The following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

a. Compounding / Dispensing Area: means any area in a prescription drug outlet where "compounding / dispensing" is performed.

b. In-State Prescription Drug Outlet: means any prescription drug outlet located within Colorado that is registered pursuant to CRS Title 12, Article 22, where prescriptions are compounded and dispensed.

c. Non-Resident Prescription Drug Outlet: means any pharmacy outlet located outside this state that is registered pursuant to CRS Title 12, Article 22, which ships, mails, or delivers, in any manner, drugs or devices into this state pursuant to a prescription order.

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 in-state or non-resident prescription drug outlet, for a transfer of ownership of an in-state or non-resident prescription drug outlet, or for the relocation of an in-state or non-resident 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 pharmacist 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 in-state or non-resident prescription drug outlets may occupy the same physical space. If there are two (or more) registrants co-located within the same building or at the same address, each must have its own area, separated by floor to ceiling walls, and separate entrances.

5.00.40 Transfer of Ownership. Application to transfer registration of an in-state or non-resident prescription drug outlet shall be submitted to the board as provided in CRS12-22-119, immediately upon the transfer of ownership. A transfer of ownership shall be deemed to have occurred:

a. In the event the in-state or non-resident 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 in-state or non-resident 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 in-state or non-resident 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 in-state or non-resident prescription drug outlet.

5.00.50 Relocation. In the event of a relocation of an in-state or non-resident prescription drug outlet, the outlet shall submit an application provided by board along with the prescribed fee at least 30 days prior to the effective date of relocation.

5.00.55 REINSTATEMENT OF AN IN-STATE OR NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION.

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

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

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

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

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

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

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

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

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

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

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

(2) A verification of the current pharmacy license or registration issued by the resident state board of pharmacy;

(3) If the registration has expired for more than two years, a copy of a report detailing an inspection of the non-resident prescription drug outlet by its resident state board of pharmacy dated within 2 years of submission of the reinstatement application.

5.00.60 Discontinuance.

a. Discontinuance shall mean the permanent cessation of the practice of pharmacy in any in state or non-resident prescription drug outlet. For in-state prescription drug outlets, discontinuance shall also be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in 5.01.40(a).

b. Upon the discontinuance of the practice of pharmacy in any in-state or non-resident prescription drug 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.

c. 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.

5.00.70 Change in Pharmacist Manager.

a. An in-state and non-resident prescription drug outlet shall be under the direct charge of a pharmacist manager. A proprietor who is not a pharmacist shall comply with this requirement and shall provide a manager who is a pharmacist.

b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within fourteen days after termination of the former

manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefore.

5.00.80 Disclosure. Any board registered non-resident prescription drug outlet shall disclose to the board, in writing, the location, names, and titles of all principal entity officers and all pharmacists who are dispensing drugs to residents of this state on an annual basis and within thirty days after any change of office, officer or pharmacist.

5.01.00 Prescription Drug Outlets (IN-STATE).

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 Compounding/Dispensing Area (In-State)

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.

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

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

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

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

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

(C) Unless the door is used to secure a room dedicated to storing controlled substances, it shall not have the ability to be locked or otherwise secured. The Board or its representatives shall have readily available and unimpeded access to this room at all times during normal business hours; and

(D) If a locked or otherwise secured door is used to secure a room dedicated to storing controlled substances, it shall be unlocked immediately upon the request of the Board or its representatives.

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. 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) All parts of CRS Title 12, Article 22; the Pharmaceuticals and Pharmacists Act.

(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) If compounding sterile products, Guide to Parenteral Admixtures or Handbook on Injectable Drugs or other comparable references as determined by the pharmacist manager;

(6) If compounding cytotoxic products, Technical Manual Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs or ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs; and

(7) 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.

5.01.33 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.

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.

5.01.50 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. 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 or left unsecured from unauthorized entry when the pharmacist leaves the building, the pharmacist manager shall notify the Board of Pharmacy in writing within ten days of the discovery of the occurrence. This written notice shall state:

(1) The name of the person authorizing the opening of the compounding/dispensing area if known, or the name of the pharmacist responsible for securing the compounding/dispensing area from unauthorized entry;

(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.

6.00.00 PHARMACEUTICAL CARE, DRUG THERAPY MANAGEMENT AND PRACTICE BY PROTOCOL.

6.00.10 Definitions.

a. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health care professionals to attain the desired outcome. This function includes efforts to prevent, detect, and resolve medication related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority.

b. Drug therapy management means the review and evaluation of drug therapy regimens for patients undertaken by a pharmacist in order to provide drug therapy, monitor progress, and modify drug therapy. Drug therapy management may only be undertaken pursuant to an initial diagnosis made by a physician, a valid order for the therapy, and a written agreement, which delineates proper protocols, to be used and the type of interaction that must occur between the pharmacist and the physician. Therapeutic interchange programs in inpatient and group model integrated closed HMO settings that are approved by medical staff committees are not considered drug therapy management for purposes of these regulations.

c. Drug therapy management may include:

1. Collecting and reviewing patient drug histories;

2. Obtaining and checking vital signs;

3. Ordering and evaluating the results of laboratory tests directly, related to management of the drug therapy when performed in compliance with the protocol ordered by the physician;

4. Modifying drug therapy, when appropriate, in compliance with the protocol ordered by the physician; and

5. Implementing the drug therapy plan agreed upon between the physician and the

pharmacist, using protocols and managing the therapy according to those protocols.

d. Protocol means a specific written plan for a course of medical treatment containing a written set of specific directions created by the physician, groups of physicians, hospital medical committee, or pharmacy and therapeutics committee.

1. Protocols must describe the nature and scope of drug therapy management appropriate for certain conditions or diagnoses, and include specific directions for the drug to be used, the specified dosage regimen, dosage forms or route of administration which are authorized. Protocols must include clear criteria and specific directions pharmacists are to follow when implementing and monitoring drug therapy. If the protocol includes ordering and evaluating laboratory tests, the protocol must provide precise instruction as to what tests are to be ordered, the criteria for ordering the tests, how the tests are to be interpreted, and what action the pharmacist is to take dependent upon the test results. If the protocol includes modifying drug therapy, the protocol must provide precise instruction as to the criteria dictating a change, and exactly how the therapy is to be changed.

2. Protocols without specific directions regarding patient treatment or those that are nonspecific, vague, or rely on discretion without definition, are insufficient and may not be used in drug therapy management by the physician or the pharmacist.

3. Protocols must also include specific instructions for responding to acute allergic or other adverse reactions. The protocols shall be signed and dated by the authorizing physician or chairperson of the authorizing group or committee.

4. Evidence based protocols. Protocols used by physicians and pharmacists engaging in drug therapy management must demonstrate a plan of treatment that constitutes evidence-based medicine. This means that the plan of treatment must be guided by or based on current, objective, supportive scientific evidence as published in scientific literature rather than anecdotal observations. Through the use of such protocols, drug therapy management must provide care that meets the standard of care in both professions.

5. The protocols shall be signed and dated by the authorizing physician or chairperson of the authorizing group or committee.

e. Agreement means a written agreement between a Colorado licensed pharmacist and a Colorado licensed physician, or a group of Colorado licensed pharmacists and a group of Colorado licensed physicians that sets forth the specific information required to assure the competent practice of pharmacy in an integrated health care fashion. Either party may withdraw from the agreement at any time.

6.00.20 Drug therapy management requirements for all practice settings.

a. Drug therapy management may only be conducted by a pharmacist upon the presentation of a valid order for a specific, individual patient from that patient's physician. The order must specify the protocol to be used, and the protocol must either accompany the order, or otherwise be provided to the pharmacist in advance of starting drug therapy management.

b. The pharmacist must ensure that the physician with whom the pharmacist is working is licensed in Colorado, in good standing, and the protocols used are within the scope of the

physician's current practice.

c. Prior to initiation of drug therapy management in any setting, the pharmacist or institution must inform the patient that he/she may refuse to participate in drug therapy management. Inpatient or group model integrated closed HMO settings may use the patient's signature on the institution's general consent to treat as the patient's indication to participate in drug therapy management.

d. At a minimum the written agreement for carrying out drug therapy management between physicians and pharmacists shall be reviewed annually, and revised, if necessary.

e. Pharmacists may perform by protocol all aspects of drug therapy management referenced in 6.00.10 b and c, provided the protocol complies with 6.00.10 d, and the pharmacists performing these functions are qualified as set forth in section 6.00.30 and are working pursuant to a written agreement with an appropriately qualified physician.

f. Filing requirements.

1. Pharmacists engaging in drug therapy management must maintain a current copy of the written agreement between the physician and the pharmacist at the location where drug therapy management is occurring. Pharmacists conducting such therapy in inpatient settings or group model integrated closed HMO's shall maintain a current copy of the general authorization plan as required by 6.00.40 at the location where drug therapy management is occurring. Upon request by the Board or its inspectors such written agreements and general authorization plans shall be submitted to the board.

2. Pharmacists practicing drug therapy management must also provide the Board documentation of their successful completion of all qualification requirements as set forth below in 6.00.30 upon request. Copies of pharmacy degrees are not required. Copies of completion of residency or other educational programs or certifications must be on file in the location of practice. Attestations from the supervising pharmacist or physician for clinical practice must be on file.

3. Pharmacists practicing drug therapy management must have a copy of the pertinent protocols at the location at which they are practicing. Upon request by Board inspectors, pharmacists must produce the scientific literature upon which their protocols are derived.

6.00.30 Pharmacist Qualifications.

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

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

b. Meet one of the following qualifications:

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

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

practice; or

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

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

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

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

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

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

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

6.00.40 Drug Therapy Management in Inpatient and Group Model Integrated Closed HMO Settings.

a. Pharmacists engaging in drug therapy management in inpatient and group model integrated closed HMO settings must conduct activities pursuant to a valid order and must follow the protocols set forth by the hospital medical committee, or pharmacy and therapeutics committee. They must record all of the items required in subsection c. below for each patient, or the hospital may create a general authorization plan, identifying where such information will be located, and how it will be accessed throughout the facility by participating pharmacists and physicians. The general authorization plan serves as the pharmacist/physician agreement in these settings. The general authorization plan must identify which physicians and pharmacists are authorized and have agreed to participate in the facility to engage in drug therapy management. The hospital medical committee or pharmacy & therapeutics committee serves as the authorizing agent for the organization's medical staff, identifying which physician groups are authorized to participate, and may restrict authorization for certain protocols to specific physician groups or specialties. A pharmacist engaging in drug therapy management must read, sign and date the plan and the pertinent protocols that he/she agrees to use in the cases undertaken.

b. The pharmacist manager shall ensure that the general authorization plans for drug therapy management are on file in the prescription drug outlet. Changes to the plan must be made as they occur, including the identification of persons participating. Protocols shall

be onsite where the drug therapy management takes place and revised as medically necessary.

c. Prior to initiation of drug therapy management, the pharmacist must review the following information:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from physician);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Emergency contact number.

d. Records of all activity by the pharmacist shall be documented in the patient's chart prior to administration.

e. Pharmacists engaging in drug therapy management shall not delegate drug therapy management activities to any other staff.

6.00.50 Drug Therapy Management in other settings.

a. Every pharmacist or group of pharmacists engaged in drug therapy management in an outpatient setting must have a valid order from the patient's physician for each specific patient for such therapy, and must operate according to a written agreement and protocol referenced in section 6.00.10.

b. Written agreements shall contain the following information:

1. Pharmacist name;

2. Physician's name;

3. Diagnoses relevant to the drug therapy to be managed and other patient conditions relevant to maintenance of the patient's health during drug therapy management;

4. Protocols to be employed;

5. Functions and activities the pharmacist will perform, and restrictions or limitations on the pharmacist's management;

6. Method, content and frequency of reports to the physician;

7. Manner in which pharmacist's drug therapy management will be monitored by the physician, including method and frequency;

8. A specified time, not to exceed 24 hours, within which the pharmacist must notify the physician of any modifications of drug therapy;

9. A provision that allows the physician to override any action taken by the pharmacist when the physician deems it to be necessary;

10. An effective date of the agreement, and signatures of both parties.

11. A provision addressing how drug therapy management will be handled when the patient has more than one physician involved in evaluating or treating the medical condition which is the subject of the agreement. All physicians who are actively involved in the management of the relevant conditions shall be parties to the agreement.

c. Prior to implementation of drug therapy management, pharmacists shall secure the following information:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from physician);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Emergency contact number.

d. Pharmacists engaging in drug therapy management shall not delegate drug therapy management responsibilities to any other staff.

6.00.60 Recordkeeping.

a. Pharmacists must document all actions taken in drug therapy management, including but not limited to any data required by the protocol. Records of each patient visit must be transmitted to the physician in the manner specified in the agreement. Records must indicate when and how the record was transmitted to the physician.

b. Pharmacists must keep patient records that include:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from physician);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Date and time the service was rendered;

8. Type of service rendered;

9. Results of interviews with the patient and any diagnostic tests or other pertinent information about the patient's disease;

10. When and how the record was transmitted to the physician; and

11. Emergency contact number.

6.00.70 Retention of Records.

a. All records of drug therapy management shall be retained for a minimum of seven years from the last date of drug therapy management, or seven years from the patient's 18th birthday, whichever is later. Such records shall be available for inspection by the patient, the physician, the Board of pharmacy, or any other authorized local, state, or federal law enforcement or regulatory agency.

b. Records may be maintained in an alternative data retention system, such as a data processing system or direct imaging system provided that:

1. The records maintained in the alternative system contain all of the information required on the manual record;

2. The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or of other authorized local, state, or federal law enforcement or regulatory agencies;

3. A back-up is conducted of the data processing system every 24 hours; and

4. The records are immediately available for the previous two years.

6.00.90 Confidentiality.

a. The pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to do so by the patient.

b. Patient information is confidential and may be released only as authorized by state and federal law. All protected health information obtained and maintained, including that obtained from the physician or other providers, must be strictly controlled in accordance with the requirements of HIPPA and other federal and state laws. Specifically, pharmacists can only release patient information to:

1. The patient or the patient's agent;

2. A practitioner or another pharmacist if, in the pharmacist's professional judgment, the release is necessary to protect the patient's health and well-being;

3. The Board or to a person or another state or federal agency authorized by law to receive the confidential record;

4. A person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; and/or

5. An insurance carrier or other third party payer authorized by the patient to receive the

information.

6.01.10 Participation Not Mandatory.

a. No person or entity, as a condition of employment, participation on an insurance provider panel, or otherwise, shall require any physician to participate in or authorize drug therapy management.

6.01.20 Board Review.

a. Board staff will review compliance with this rule and report to the Board regarding complaints and other relevant data associated with the rule every three years.

7.00.00 PHARMACIST MANAGER RESPONSIBILITIES. [Eff. 11/30/2008]

7.00.10 Reporting Violations. The pharmacist manager of a prescription drug outlet shall report to the board, in writing, within the timelines set forth in the relevant rules and statutes, the following violations of the Pharmaceuticals and Pharmacists 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. In such instance the report shall be submitted to the board immediately upon discovery.

e. Significant errors related to the practice of pharmacy, including those related to compounding, such as those that result in serious personal injury or death of a patient. In such instance the report shall be submitted to the board immediately upon discovery.

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. 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 11.00.00.

I. It is the responsibility of the pharmacist manager to maintain records of initial interpretation and final evaluation as required by regulation 3.00.51(a) and (b).

J. It is the responsibility of the pharmacist manager to maintain and to assure the outlet's compliance with a policy and procedure manual, where applicable, encompassing all aspects of non-sterile and sterile compounding as required by regulations 21.10.10 and 21.20.30, respectively. The annual review of such manual or manuals shall be signed and dated by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within 30 days of becoming the pharmacist manager.

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.

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

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

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

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

4. Documentation that the pharmacy technician does not have certification from a

nationally recognized certification Board, has not graduated from an accredited pharmacy technician training program, and has not completed 500 hours of experiential training at the pharmacy.

c. The pharmacist manager is responsible for ensuring that all prescription drugs and controlled substances are procured by the outlet from an entity or person registered by the Colorado State Board of Pharmacy. Any drug designated as an Investigational New Drug from the Federal Food and Drug Administration is exempt from this requirement provided the research requirements for the receipt of the product are followed and it meets the requirements of CRS 12-22-128(2).

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. In the case of a central fill prescription processing contract, the label shall contain at least the name and address of the originating pharmacy.

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. [Eff. 04/30/2009]

9.00.10 Reporting.

a. A licensee or registrant shall notify The board in writing within 72 hours of the licensee or registrant receiving service of process or knowledge by other means of any legal proceedings in Colorado or anywhere wherein it is alleged that the licensee or registrant has violated any law or regulation pertaining to drugs or devices. This includes civil malpractice cases.

1. The notice to the board shall include the following information:

(a) The court;

(b) The jurisdiction;

(c) The case name;

(d) The case number; and

(e) A description of the matter and a copy of the indictment or charges.

2. The licensee or registrant shall notify the board in writing within 30 days of the disposition of such proceeding.

b. All licensees or registrants shall notify the Board in writing within 30 days of any disciplinary action against them in another state. Such notification shall include the following:

1. The state;

2. The jurisdiction;

3. The case name;

4. The case number;

5. A description of the matter and a copy of the indictment or charges;

6. A copy of the discipline; and

7. Proof of completion of any requirements set forth in the order, if applicable.

c. All licensees or registrants shall notify the board in writing of any criminal conviction or deferred judgment against them (including, but not limited to, “driving under the influence” and “driving while ability impaired”), and petty offenses within 30 days after such conviction or judgment.

1. For purposes of this rule, a “conviction” includes:

(a) A guilty verdict;

(b) A plea of guilty accepted by the court;

(c) A plea of nolo contendere (no contest) accepted by the court; or

(d) A deferred judgment or sentence.

2. The notice to the board shall include the following information:

(a) The court;

(b) The jurisdiction;

(c) The case name;

(d) The case number;

(e) A description of the matter and a copy of the indictment or charges;

(f) A copy of the plea agreement or verdict; and

(g) Proof of completion of court ordered requirements, if applicable.

d. The registrant or licensee notifying the board may submit a written statement with any notice required under this rule to be included in the registrant or licensee records.

e. Each insurance company licensed to do business in Colorado and engaged in the writing of malpractice insurance for licensed pharmacists and each pharmacy that self-insures shall send to the board, in the form prescribed by the board, information relating to each malpractice claim against a licensed pharmacist which is settled or in which judgment is rendered against the insured. Such information shall be provided to the board within 30 days of the settlement or judgment.

10.00.00 EMERGENCY KITS.

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

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

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

10.00.20 Categories and Limits

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

b. In the case of a Certified Home Health Agency or an Outpatient Hospice, the director of nursing of the Certified Home Health Agency or of the Licensed Hospice, and a pharmacist employed and designated by the prescription drug outlet or hospital other outlet providing the kit shall determine the specific drugs to be kept in the kit. A Certified Home Health Agency or Outpatient Hospice may not have oral dosage forms or controlled substances in the kit. The container size for each injectable drug shall be limited to unit dose or unit of issue packaging. The number of drugs allowed in the kit shall be limited to sixty (60). The kit may contain only thirty (30) doses of any separate drug dosage form or strength for each drug.

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

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

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

b. The date of sealing of the kit;

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

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

the name of the designated pharmacist.

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

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

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

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

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

Notification must be repeated, within 30 days:

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

or

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

10.00.60 Inspection. A pharmacist employed by the prescription drug outlet or hospital other outlet providing the kit or that pharmacist's designee shall inspect and inventory the contents of the kit at least annually and within 72 hours after being notified that the kit has been accessed. Inspection shall be documented by that pharmacist, and such documentation shall be maintained and available for inspection at the prescription drug outlet or hospital other outlet for a period of two years.

10.00.70 Records. The prescription drug outlet or hospital other 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 following:

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

b. The name and strength of the drug; and

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

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

a. Date and quantity administered;

b. Names of both the patient and practitioner;

c. Date the drug was replaced in the kit;

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

e. The prescription order number assigned.

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

11.00.00 RECORDS AND RECORDKEEPING.

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

All such records shall be retained for a period of at least two years after the date of any transaction relating to such record or inventory by any process providing an exact duplicate of the original order in a reproducible quality acceptable to the Board. Records shall be retained in a format that cannot be altered.

Records on an automated data processing system or subsequent storage of such records must be immediately retrievable (via monitor display or hard copy printout). Upon written Board approval, outlets capable of meeting the above standards may not be required to retain the original prescription order or LTCF chart order for non-controlled drugs.

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

For all Registered Prescription Drug Outlets:

a. The following records shall be maintained on the premises of the prescription drug outlet at all times, unless written authorization for off-site storage has been approved by the board, and shall be made available for inspection by the Board or its inspectors immediately upon request:

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

(2) All inventories of controlled substances required to be taken during the two years

preceding the request;

(3) All prescription orders or LTCF chart orders dispensed during the two years preceding the request;

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

(5) All lists as required by regulations 11.08.00 and 11.09.00.

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

(1) All unexecuted DEA-222 forms.

(2) Specific records requested by the inspector if the inspector determines the records are not maintained in a readily retrievable manner.

(3) Records of receipt of non-controlled prescription drugs.

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

a. If the outlet is registered with the Drug Enforcement Administration as a “hospital/clinic” , the inventory shall include all drugs located throughout the facility, excluding any drug which has been dispensed pursuant to a lawful chart order but which has not yet been administered to the patient.

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

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

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

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

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

(1) The name of the drug;

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

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

(4) All outdated controlled substances.

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

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

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

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

11.04.00 Records pertaining to prescription orders and chart orders for long-term care facility patients (LTCF chart orders).

11.04.10 A hard copy of every prescription order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such prescription order unless the prescription drug outlet has received written Board approval to not retain the original prescription order for non-controlled drugs and Schedule III, IV, and V Controlled Substances. Prescription orders will be deemed to be readily retrievable and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to 2.01.10. In addition to being filed in numerical sequence, three different prescription files shall be maintained: one file shall consist only of schedule II controlled substance prescription orders; the second file shall consist only of schedule III, IV and V controlled substance prescription orders; and the third file shall consist of all non-controlled substance prescription orders. Filing of prescription orders in any manner other than by numerical sequence will result in such prescription orders being deemed not readily retrievable and available.

A hard copy of every chart order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order. The LTCF chart orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing. Chart orders for schedule III, IV, and V controlled substances shall be readily identifiable from non-controlled chart orders. Schedule II orders shall be retained separately from all other orders.

If a prescription drug outlet utilizes both prescription orders and chart orders, assigning serial numbers to both with the same computer system, the orders must be filed sequentially by serial number.

11.04.20 Computer Use With Prescription Order or LTCF Chart Order Transactions. *[Eff. 11/30/2008]*

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

a. All new and refill prescription and LTCF chart order transactions shall be entered into the system at the time of the transaction, except as provided in regulation 11.04.20(i).

b. Every 24 hours, except as provided in regulation 11.04.30, the system must produce a hard-copy document which, for the purposes of these regulations, shall be known as the “daily printout” . It shall consist of a single, uniform, complete document, except as otherwise permitted in this regulation. The daily printout shall list, separately, each prescription or LTCF chart order transaction for the previous 24 hours and shall contain all information required by this regulation. Daily printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages which are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable and available.

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

(1) The serial number;

(2) The name of the patient;

(3) The name of the practitioner:

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

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

(6) The total number of refills authorized;

(7) Date dispensed;

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

(9) The quantity of the drug dispensed;

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

d. Records of prescription or LTCF chart order transactions involving controlled substances shall be identifiable from those involving non-controlled substances. Alternatively a separate complete printout listing only controlled substance transactions may be produced.

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

f. Prescription or LTCF chart order refill transactions must be uniformly recorded on the original prescription or LTCF chart order or on the daily printout. In the event of a discrepancy between the entry on the order and the entry on the daily printout, the information recorded on the daily printout shall be deemed to be correct.

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

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

Or

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

h. The daily printout shall contain all information as required by this 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 outlet 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.

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

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

11.04.30 Electronic Maintenance of Prescription or LTCF Chart Order Records. *[Eff. 11/30/2008]*

A prescription drug outlet which utilizes a computer (automated data processing system) for storage and retrieval of information regarding prescription or LTCF chart order transactions need not print the daily printout required by regulation 11.04.20 if the prescription drug outlet and the computer system utilized are capable of complying with the following requirements:

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

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

c. The prescription drug outlet must:

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

Or

(2) Have a “lock-out” feature that prevents editing of dispensing information.

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

(1) Print a report of all prescription or LTCF chart order transactions for such period of time as the Board of its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally within 72 hours, the system must be capable of retrieving and printing the information sorted according to the variables which include, but are not limited to, date dispensed; drug name, strength and dosage form; patient name, and practitioner name; or

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

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

e. Whether the prescription drug outlet elects to comply with regulation 11.04.30 (d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:

(1) The prescription order serial number;

(2) The name of the patient;

(3) The name of the practitioner;

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

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

(6) The total number of refills authorized;

(7) Date dispensed;

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

(9) The quantity of the drug dispensed;

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

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

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

11.05.00 Records Pertaining to Hospital Chart Orders.

11.05.10 A chart order or the other appropriate, uniformly maintained records permitted by regulation 2.01.20 (c) shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order or record. However, if the records permitted by regulation 2.01.20 (c) and 11.05.20 are retained and are complete, the prescription drug outlet copy of a chart order need not be retained. Prescription drug outlet copies of chart orders or the other appropriate, uniformly maintained records permitted by 2.01.20 (c) and 11.05.20 will be deemed to be readily retrievable and available if they are filed:

a. In chronological order according to the date of discharge of the patient; or

b. Alphabetically by patient surname by month of discharge; or

c. By date of dispensing transaction.

Filing of chart order/dispensing transaction record in any other manner will result in such orders or records being deemed not readily retrievable and available.

11.05.20 Records Pertaining to Chart Orders Shall Contain the Following Information:

a. The identity of the pharmacist making the initial interpretation;

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

c. The quantity dispensed and

d. The date of dispensing;

e. Any record of a controlled substance dispensed pursuant to a chart order for and individual patient shall be visually identifiable from records of non controlled substances.

11.05.21 It is permissible to store different types of chart order dispensing records separately. For the purpose of this regulation, different types of chart order dispensing records include fill lists, records of compounded injectable products, records of the initial dispensing of a chart order, and the records of redispensing of chart orders. If the prescription drug outlet chooses to maintain different types of dispensing records separately, they must be maintained as required by regulation 11.05.10.

11.05.30 Computer Use with Hospital Chart Order Transactions. A prescription drug outlet may utilize a computer (automated data processing system) for storage and retrieval of information regarding chart order transactions if the following requirements are met:

a. All new chart orders shall be entered into the system, except as provided in regulation 11.05.30 (e). For the purpose of this regulation, “dispensing transaction” is defined as delivery of a drug or device pursuant to a chart order.

b. All records produced by this computer system must comply with regulation 11.05.20. These records shall be printed a minimum of every 24 hours unless the prescription drug outlet

complies with regulation 11.05.40. This documentation shall be retained for at least two years from the date of dispensing. This documentation shall be retained in a chronological manner. If printouts are bound, the sheets shall be separated into individual pages, which are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable. This documentation shall be available for inspection by the Board or its inspectors within 72 hours from the most recent date recorded on the documentation.

c. Any computer system utilized shall have the capability of producing a single-document printout, which shows for any controlled substance a complete history of all dispensing transactions during the previous two years for each patient admission. This printout shall be available within 72 hours of a request by the Board

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

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

11.05.40 Electronic Maintenance of Hospital Chart Order Records. A prescription drug outlet which utilizes a computer (automated data processing system) for storage and retrieval of information regarding chart order transactions need not print the records of chart order dispensing required by regulation 11.05.20, if the prescription drug outlet and the computer system utilized are capable of complying with the following requirements.

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

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

c. The prescription drug outlet must:

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

or

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

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

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

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

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

e. Whether the prescription drug outlet elects to comply with regulation 11.05.40 (d) (1) or (2), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:

(1) The name and/or other identifying factor of the patient;

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

(3) The quantity dispensed;

(4) The date of dispensing;

(5) Any record of a controlled substance dispensed pursuant to a chart order for an individual patient shall be distinguishable from records of non-controlled substances. Alternatively, a separate complete printout listing on controlled substance transactions may be produced.

f. The daily printout shall contain all information as required by this 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 outlet 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.

11.06.00 Receipts *[Eff. 03/02/2009]*

11.06.05 All prescription drugs and controlled substances received by a prescription drug outlet shall only be procured from another entity or person registered by the Colorado State Board of Pharmacy.

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

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received;

f. Name of the labeler of the drug and/or NDC number of the drug if it is labeled only with its generic name;

g. Name and address of the distributor;

h. Name and address of the receiving outlet;

i. DEA number of distributor and receiver if a controlled substance; and

j. If a schedule II controlled substance, The DEA form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other.

11.06.20 All records of receipt (including credit invoices) of prescription drugs and controlled substances shall be maintained for a period of time not less than two years from the date the drugs were received. Hard copy records of receipt (including credit invoices) of non-controlled prescription drugs need not be maintained on the premises provided that they shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors.

11.06.30 All records of receipt of schedule II controlled substances shall be maintained separately from all other records and be readily available for inspection in hard copy form at the outlet for a period of time not less than two years from the date the drugs were received.

11.06.40 All records of receipt of schedule III, IV, and V controlled substances shall be maintained separately from all other records and shall at all times be maintained and readily available for inspection in hard copy form at the outlet for a period of time not less than two years from the date the drugs were received.

11.06.50 Records detailing the receipt of prescription drugs, as required by regulation 11.06.10(a) through (h), may be maintained electronically if the following requirements are met:

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

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

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

d. The board or its inspectors must be able to inspect and review all of the prescription drug receipt transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the board or its inspectors, the outlet shall either:

(1) Print a report of all prescription drug receipt transactions for a period of time as the board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours;

Or

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

(3) It is the responsibility of the pharmacist manager of the outlet to ensure that all outlet

staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the pharmacist manager and/or staff to comply with a request by the board or its inspector(s) will be deemed to be a willful violation of these regulations.

e. If the outlet chooses to maintain records detailing the receipt of prescription drugs electronically, any reports printed upon the request shall contain, at a minimum, the following information for each receipt transaction:

(1) Name of the drug;

(2) Strength of the drug;

(3) Dosage form if appropriate;

(4) Quantity of the drug received;

(5) Date received;

(6) Name of the labeler of the drug and/or NDC number of the drug if it is labeled only with its generic name;

(7) Name and address of the distributor; and

(8) Name and address of the receiving outlet.

11.07.00 Distribution

11.07.10 Records of distribution of controlled substances and prescription drugs within hospitals. Records of distribution of controlled substances and prescription drugs shall comply with the following:

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

(1) The location receiving the drug;

(2) The name of the drug;

(3) The strength of the drug;

(4) The quantity of the drug;

(5) The dosage form if appropriate;

(6) The date the drug was supplied;

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

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

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

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

(2) The prescription drug outlet must:

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

or

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

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

(a) Print a report of all distribution transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date distributed, drug name, strength and dosage form, or

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

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

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

(a) The location receiving the drug;

(b) The name of the drug;

(c) The strength of the drug;

(d) The quantity of the drug;

(e) The dosage form if appropriate;

(f) The date the drug was supplied;

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

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

11.07.20 Records of Distribution/Casual Sale of Controlled Substances and Prescription Drugs. A prescription drug outlet which distributes prescription drugs and/or controlled substances shall record the following: *[Eff. 11/30/2008]*

a. The name of the drug;

b. The strength of the drug;

c. The dosage form, if appropriate;

d. The quantity of the drug;

e. The name of the manufacturer or the NDC number of the drug if labeled only with its generic name. In the case of a compounded product, the name of the pharmacy shall be recorded;

f. If a compounded product, the batch or lot number;

g. The date of distribution;

h. The name and address of the distributing outlet;

i. The name and address of the receiver;

j. If a controlled substance is distributed, the record shall also indicate the Drug Enforcement registration number of the distributing outlet and the receiver;

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

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

11.07.21 These records of distribution and casual sale required by 11.07.20 shall be retained for a period of time not less than two years from the date of the distribution.

11.07.22 Records of distribution and casual sale required by regulation 11.07.20 may be maintained electronically if the following requirements are met:

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

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

c. Have a “lock-out” feature that prevents editing of distribution and casual sale information.

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

(1) Print a report of all distribution and casual sale transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to; date of distribution, drug name, strength and dosage form, and licensee receiving the distribution;

or

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

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

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

(1) The name of the drug;

(2) The strength of the drug;

(3) The dosage form if appropriate;

(4) The quantity of the drug;

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

(6) The date of distribution;

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

(8) The name and address of the receiver;

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

11.08.00 List of Employees. Each prescription drug outlet shall keep and maintain on a current basis a list of every licensed pharmacist and intern who has practiced pharmacy in that outlet at any time

during the previous two years, including all part-time or relief personnel. This list shall show, for each such person, the following information:

a. The printed name of the person;

b. The person's license number;

c. A sample of his/her initials and signature and any other identifying mark as affixed to any record required by law or regulation; and

d. The date upon which such person began practicing pharmacy in the prescription drug outlet.

11.09.00 Symbols and Codes. Symbols and codes may be used to identify any manufacturer, distributor or repackager. If such symbols and codes appear in the records of a prescription drug outlet, the prescription drug outlet shall keep a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable and available for examination by the Board for at least two years.

12.00.00 NUCLEAR PHARMACY. [Eff. 11/30/2008]

12.00.10 Authorized handling. It is unlawful to receive, possess or transfer radiopharmaceuticals, except in accordance with CRS 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 CRS 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 CRS 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 CRS 25-11-101.

12.00.22 "Nuclear pharmacist" means a pharmacist who holds an active pharmacist license with the board and has met the standards of training and experience for "Authorized User Status" in handling radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission.

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 All nuclear prescription drug outlets 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 separate from and exclusive of the radioactive laboratory, compounding, dispensing, quality assurance and administrative area. Prior to registration, a nuclear prescription drug outlet that wishes to compound both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies shall meet the space requirements set forth in Regulation 5.01.31. If a nuclear prescription drug outlet wishes to compound only radiopharmaceuticals, it shall not be required to meet the space requirements set forth in Regulation 5.01.31. All nuclear prescription drug outlets shall submit detailing drawing-to-scale floor plans to the board that have been approved by the state radiation control agency before approval of the registration.

12.00.32 Nuclear prescription drug outlets that compound both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies shall maintain a professional library in compliance with regulation 5.01.31(f), regulation 12.00.32(a) through (d), and if applicable, regulation 5.01.32(a)(3). A nuclear prescription drug outlet that compounds only radiopharmaceuticals shall maintain and have available in the outlet or electronically a professional library in compliance with regulation 12.00.32(a) through (d) and shall be exempt from the requirements of regulation 5.01.31(f) and 5.01.32(a)(3). If an electronic library is provided, workstations must be provided and must be readily available for use by staff 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:

a. All parts of CRS Title 12, Article 22;

b. The current rules and regulations of the board of pharmacy;

c. The current rules and regulations of the State Radiation Control Agency and U.S. Nuclear Commission; and

d. Any other references that the pharmacist manager of the nuclear prescription drug outlet deems necessary.

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.

12.00.35 Nuclear prescription drug outlets which compound and dispense only radiopharmaceuticals shall be exempt from the security requirements of regulation 5.01.50 provided the following conditions are met:

a. Only individuals identified as having "Authorized User" status by the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission may enter the compounding/dispensing area in the absence of a pharmacist and only for the purpose of equipment maintenance.

b. The nuclear prescription drug outlet maintains a written record documenting such entry detailing the following information:

1) Date and time of entry;

2) Authorized users name;

3) Reason for entry; and

4) Signature of pharmacist manager.

Such record shall be maintained on the premises and available for inspection for at least two years from the date of entry.

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

a. Be a pharmacist licensed to practice in Colorado;

b. Meet the standards of training and experience for "authorized user status" in handling of radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission; and

c. Be specifically identified, by name, as an "authorized nuclear pharmacist" on either a radioactive materials license issued by the Colorado Department of Public Health and Environment or on a U.S. Nuclear Regulatory Commission master license.

12.00.45 Nuclear prescription drug outlets shall post, in a conspicuous area of the compounding / dispensing area of the outlet, and shall have readily available for inspection, the follow:

a. The original copy of the current registration with the pharmacy board;

b. The original copy, or a reference to its specific location in the outlet, of the most current radioactive materials license issued by the Colorado Department of Public Health and Environment;

c. A copy, or a reference to its specific location in the outlet, of the most current U.S. Nuclear Regulatory Commission master license which details a listing of its authorized nuclear pharmacists if the current radioactive license issued by the Colorado Department of Public Health and Environment references the outlet's U.S. Nuclear Regulatory Commission master license rather than detailing a listing of the outlet's authorized

nuclear pharmacists itself; and

d. The outlet's current list of employees that complies with regulation 11.08.00.

12.00.64 Nuclear Compounding.

If a nuclear pharmacist compounds a preparation according to the manufacturer's labeling instructions, then further documentation is not required. All other compounded preparations require further documentation.

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

b. The compounding of sterile radiopharmaceuticals shall comply with regulation 21.00.00, including all recordkeeping requirements.

12.00.70 Dispensing.

a. A radiopharmaceutical shall only be dispensed pursuant to a valid, patient-specific prescription order that is issued by an authorized practitioner.

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

c. 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;

(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) Expiration data, if applicable.

d. The immediate inner container shall be labeled with:

(1) The standard radiation symbol;

(2) The words "caution – radioactive material";

(3) The assigned serial number of the corresponding prescription order; and

(4) The name of the radiopharmaceutical.

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

12.00.71 Records of Dispensing.

a. In addition to any requirement of the board for non-radiopharmaceutical prescription orders, the prescription order shall include the following:

(1) Address of the authorized practitioner and/or the address where the prescription is to be administered;

(2) The name of radiopharmaceutical;

(3) The amount of radioactive materials contained, in millicuries or microcuries; and

(4) Calibration time for the amount of radioactivity contained.

For the purposes of this regulation, the prescription drug outlets may record the address on the order or maintain it in a readily retrievable format.

b. A hard copy of every prescription order shall be readily retrievable and available for inspection for a period of two years from the date of any transaction relating to such order. If a nuclear prescription drug outlet dispenses only radiopharmaceuticals, prescription orders will be deemed to be readily retrievable and available if they are filed according to the date of dispensing. If a nuclear prescription drug outlet dispenses both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies, all prescription orders will be deemed to be readily retrievable and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to regulation 2.01.10.

12.00.72 Distribution.

a. A nuclear prescription drug outlet may distribute a compounded radiopharmaceutical to a practitioner authorized by law to prescribe the drug for the purposes of administration. Such distributions shall be limited to up to 10 percent of the total number of drug dosage units dispensed and distributed on an annual basis by such outlet.

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

c. The immediate outer container of the radiopharmaceutical to be distributed shall be labeled with:

(1) The standard radiation symbol;

(2) The words "Caution – Radioactive Material";

(3) “RX Only” ;

(4) The name of Radiopharmaceutical;

(5) The amount of radioactive materials contained, in millicuries or microcuries;

(6) If a liquid, the volume in milliliters;

(7) The requested calibration time for the amount of radioactivity contained;

(8) Expiration data, if applicable;

(9) The assigned batch (lot) number;

(10) Specific route of administration;

(11) Storage directions; and

(12) The name and address of the prescription drug outlet.

d. The immediate inner container shall be labeled with:

(1) The standard radiation symbol;

(2) The words "Caution – Radioactive Material";

(3) The assigned batch (lot) number; and

(4) The name of the radiopharmaceutical.

12.00.73 Records of Distribution.

a. A nuclear prescription drug outlet shall maintain records of acquisition and distribution of all radiopharmaceuticals in accordance with CRS Title 12, and CRS Title 25.

b. A nuclear prescription drug outlet must retain verification of each practitioner's license from the jurisdiction in which licensed on a current basis for each practitioner to whom it distributes compounded radiopharmaceuticals.

c. A nuclear prescription drug outlet that distributes radiopharmaceuticals shall record the following:

(1) The name of the radiopharmaceutical;

(2) The amount of radioactive materials contained, in millicuries or microcuries;

(3) If a liquid, the volume in milliliters;

(4) The requested calibration time for the amount of radioactivity contained;

(5) The date of distribution;

(6) The name and address of the authorized practitioner and the address where the preparation is to be administered; and

(7) The name and address of the distributing outlet.

d. Records of distribution shall be retained at the outlet for a period of not less than two years from the date of distribution.

13.00.00 DECLARATORY ORDERS.

13.00.10 Requests. Any person 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.

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 CRS 12-22-101, et. Seq. as amended, and 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 (CRS 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 CRS 24-4-106.

14.00.00 OTHER OUTLETS.

14.00.10 General Criteria. Unless otherwise exempted, the general criteria, which shall be met by other outlets herein enumerated, which are seeking to be registered by the Board pursuant to CRS 12-22-120(1)(e), are stated below.

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

b. All prescription drugs utilized by the outlet shall be obtained from an entity or individual registered with the Colorado State Board of Pharmacy or a state or local health agency.

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

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

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

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

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

d. The duties of the consulting pharmacist.

14.00.30 Revisions to other outlet protocols. Revisions to other outlet protocols shall be submitted as a complete set in duplicate for approval by the Board. Prior to becoming effective, the protocol

changes must be approved by the Board or its designee. 14.00.40 Application Procedure.

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

b. Other outlet relocation.

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

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

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

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

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

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

(4) Upon incorporation of an existing other outlet.

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

e. Change of consultant pharmacist.

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

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

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

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

(5) A pharmacist assuming duties as a consultant pharmacist for an other outlet shall

review the current protocols and document the review within 30 days of assuming said position. Documentation shall include the date of review and the consultant pharmacist's signature. Said documentation shall be retained with the consultant pharmacist's record of inspection or the current Board approved protocols.

f. Change of Registration.

(1) Any other outlet located in a community health clinic, rural health clinic, college, or university which dispenses more than 25000 dispensing units in a calendar year shall register with the board as a prescription drug outlet.

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

14.00.40 Application Procedure.

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

b. Other outlet relocation.

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

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

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

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

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

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

(4) Upon incorporation of an existing other outlet.

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

e. Change of consultant pharmacist.

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

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

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

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

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

f. Change of Registration.

(1) Any other outlet located in a community health clinic, rural health clinic, college, or university which dispenses more than 25000 dispensing units in a calendar year shall register with the board as a prescription drug outlet.

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

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

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

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

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

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

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

14.00.80 Consultant pharmacist.

a. A consultant pharmacist shall either:

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

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

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

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

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

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

(a) Jails;

(b) County health departments;

(c) Schools, grade kindergarten through twelve;

(d) Hospitals; and

(e) Family planning clinics.

(2) Community clinics, rural health clinics, colleges, and universities shall be inspected and visited as follows:

(a) Monthly if 2500 or less dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

(b) Every other week if more than 2500 but less than 7501 dispensing units are dispensed in a calendar year; A calendar year is considered to run from January 1 through December 31.

(c) Each week if 7501 dispensing units but less than 12501 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

(d) Twice each week if 12501 dispensing units but less than 25001 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

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

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

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

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

14.00.90 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.

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

90 day period.

14.02.00 Records and recordkeeping in other outlets.

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

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

a. For all other outlets:

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

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

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

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

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

(a) All unexecuted DEA-222 forms.

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

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

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

14.02.30 Inventories of controlled substances. Any inventory of controlled substances shall comply with

the following:

a. If the outlet is registered with the Drug Enforcement Administration as a "hospital/clinic", the inventory shall include all drugs located throughout the facility, excluding any drug which has been dispensed pursuant to a lawful chart order but which has not yet been administered to the patient.

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

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

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

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

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

(1) The name of the drug;

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

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

(4) All outdated controlled substances.

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

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

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

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

14.03.00 Dispensing records.

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

(1) Unique serial number;

(2) Patient name;

(3) Prescriber;

(4) Date dispensed;

(5) Name and strength of drug dispensed;

(6) Quantity dispensed;

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

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

(9) Number of refills authorized;

(10) Number of refills dispensed to date;

(11) Identification of individual responsible for dispensing;

(12) If a controlled substance, the DEA registration number of the prescriber;

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

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

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

b. Every 24 hours, except as provided in regulation 14.03.20, the system must produce a hard-copy document which, for the purposes of these regulations, shall be known as the "daily printout". It shall consist of a single, uniform, complete document, except as otherwise permitted by this regulation. The daily printout shall list, separately, each prescription order transaction for the previous 24 hours and shall contain all information required by this regulation. Daily printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages which are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable and available.

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

(1) The serial number;

(2) The name of the patient;

(3) The name of the practitioner;

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

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

(6) The total number of refills authorized;

(7) The date dispensed;

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

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

(10) The quantity of the drug dispensed;

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

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

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

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

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

or

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

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

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

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

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

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

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

c. The other outlet must

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

or

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

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

(1) Print a report of all dispensing transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date dispensed; drug name, strength and dosage form; patient name, and practitioner name;

or

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

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

e. Whether the other outlet elects to comply with regulation 14.03.20(d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:

(1) The prescription order serial number;

(2) The name of the patient;

(3) The name of the practitioner;

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

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

(6) The total number of refills authorized;

(7) Date dispensed;

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

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

(10) The quantity of the drug dispensed;

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

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

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

14.04.00 Receipts.

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

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received if a controlled substance;

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

g. Name of the distributor;

h. DEA number of distributor if a controlled substance.

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

attached to each other.

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

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

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

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

14.05.00 Distribution.

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

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

(1) The location receiving the drug;

(2) The name of the drug;

(3) The strength of the drug;

(4) The quantity of the drug;

(5) The dosage form if appropriate;

(6) The date the drug was supplied;

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

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

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

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

(2) The other outlet must:

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

or

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

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

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

or

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

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

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

(a) The location receiving the drug;

(b) The name of the drug;

(c) The strength of the drug;

(d) The quantity of the drug;

(e) The dosage form if appropriate;

(f) The date the drug was supplied;

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

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

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

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

controlled substances shall record the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

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

f. The date of distribution;

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

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

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

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

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

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

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

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

or

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

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

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

or

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

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

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

(1) The name of the drug;

(2) The strength of the drug;

(3) The dosage form if appropriate;

(4) The quantity of the drug;

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

(6) The date of distribution;

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

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

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

14.05.24 Advertising.

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

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

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

14.06.00 Petition for a Reduced Visitation/Inspection Schedule.

a. The consultant pharmacist of an other outlet may petition the board for a reduced visitation/inspection schedule by submitting a written request to the board detailing the procedures or technology the other outlet has in place which eliminate the need for the required frequency of visitation/inspection. The board will review these requests in the ordinary course of business. No other outlet may change its visitation/inspection schedule

without receiving written notification from the board approving the outlet's alternative visitation/inspection schedule. Such written notification shall be maintained in the other outlet posted next to the other outlet registration.

14.07.00 Emergency Redistribution of Prescription Drugs

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

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

e. Lot number of the drug;

f. Expiration date of the drug;

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

h. The date of distribution;

i. The name and address of the distributing outlet;

j. The name and address of the receiver;

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

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

15.00.00 WHOLESALERS.

15.01.00 Wholesale Drugs Distributor Registration Requirement.

a. A wholesaler means any person engaged in the wholesale distribution of prescription drugs, including, but not limited to repackagers, own-label distributors, private-label distributors, jobbers, brokers, warehouses, including manufacturers' and distributors' warehouses; manufacturers' exclusive distributors; authorized distributors of record; drug wholesalers or distributors; independent wholesale drug traders; specialty wholesaler distributors; pharmacy buying cooperative warehouses; retail pharmacies that conduct wholesale distribution; and chain pharmacy warehouses that conduct wholesale distribution.

b. Every wholesaler must be registered with the Colorado State Board of Pharmacy if it resides in Colorado and distributes drugs or is located in another state or territory of the United States and ships prescription drugs into Colorado.

15.01.10 Requirements for Licensure.

15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

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

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

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

(4) The type of ownership or operation (i.e., partnership, corporation, sole proprietorship, limited liability company, or government entity); and

(5) The name(s) of the owner and operator of the applicant including:

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

(b) If a partnership, the name of each partner, the name of the partnership, and the federal employer identification number (FEIN);

(c) If a corporation, the name and title of each corporate officer and director, the name of the parent company, the corporate names, the federal employer identification number of the business, 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 and federal employer identification number of the business entity.

(e) If a government entity, identify the name of director and the name of the governmental agency he/she represents.

(6) If a limited liability company, the name and title of each member, federal employer identification number (FEIN) of the business, and name of parent company, if any.

(7) A list of the licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of

and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803.

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

b. Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

c. Any registered wholesale drug distributor that is accredited by a board approved accreditation body shall inform the board, in writing, within 72 hours if its accreditation is:

(1) Expired;

(2) Suspended;

(3) Revoked; or

(4) Withdrawn.

15.01.12 Minimum Qualifications.

a. The Colorado Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons of businesses described in 15.01.11 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 criminal or civil convictions of the applicant under federal or state laws;

(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) Disciplinary proceedings by any federal, state, or local government of any registration currently or previously held by the applicant for the manufacture, distribution or dispensing of any drugs, including controlled substances;

(6) Compliance with registration requirements under a previously granted registration, if any;

(7) Compliance with requirements to maintain and/or make available to the Colorado Board of Pharmacy or other governmental agency those records required under this 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 registration to an applicant if it determines that the granting of such a registration would not be in the public interest.

c. All applicants shall be inspected within the previous two years prior to registration. If the applicant is located in Colorado, inspectors from the Colorado state board of pharmacy shall conduct the inspection. If the wholesaler is located outside of Colorado, the board of pharmacy of the state in which the wholesaler resides shall conduct an inspection of the facility or the out of state wholesaler may be inspected by a board-approved accreditation body.

d. The Board may suspend, revoke, refuse to renew, or otherwise discipline the registration of any wholesale drug distributor if its Board approved accreditation has been suspended, revoked, or withdrawn.

15.01.13 A wholesaler must be located at a commercial location. It may not be located in a personal dwelling or residence.

15.01.14 Change of name, location, or ownership, or designated representative.

a. Any change in the name or location of the wholesaler shall be reported to the board on an application provided by the board prior to such change.

b. Any change in ownership shall be reported on an application provided by the Board within fifteen calendar 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:

(1) 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;

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

(3) In the event the 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 wholesaler.

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

15.01.17 When a wholesaler changes location, the outlet shall submit an application on a form provided by the board prior to outlet relocation.

15.01.18 Reinstatement of an Expired In-State or Out-of-State Prescription Drug Wholesaler Registration.

a. In-State Prescription Drug Wholesaler. Iif a registration has expired, a registrant wishing to reinstate such registration shall submit the following:

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

(2) A newly completed designated representative affidavit, on a form provided by the Board, that is signed and dated by the designated representative; and

(3) If a different designated representative has been established for the applicant since the expiration of the registration, the applicant shall submit the new designated representative's fingerprints to the Colorado Bureau of Investigation for both a state and federal background check at the time of submission of the reinstatement application, unless otherwise statutorily exempt or previously waived by the Board.

b. Out-of-State Prescription Drug Wholesaler. If a registration has expired, a registrant wishing to reinstate such registration shall submit the following:

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

(2) The applicant shall submit the designated representative's fingerprints to the Colorado Bureau of Investigation for both a state and federal background check at the time of submission of the reinstatement application, unless otherwise statutorily exempt or previously waived by the Board.

(3) A verification of the current prescription drug wholesaler license or registration issued by the resident state board of pharmacy;

(4) A newly completed designated representative affidavit, on a form provided by the Board, that is signed and dated by the designated representative; and

(5) If the registration has expired/lapsed for over 2 years, a registrant shall submit one of the following:

(A) A copy of a report detailing an inspection of the out-of-state prescription drug wholesaler by its resident state board of pharmacy dated within 2 years of submission of the reinstatement application; or

(B) A current copy of the wholesaler's accreditation by a board-approved accreditation body; or

(C) Proof of the wholesaler's current registration with the Federal Food and Drug Administration (FDA).

15.02.00 Personnel.

15.02.10 Designated Representative. 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 and devices. This person's name, social security number, and title shall be reported to the Board in writing.

15.02.11 Wholesalers shall certify that all staff, employees, personnel have suitable education or experience for the position such staff and employees hold and the job functions they are assigned. The wholesaler shall affirm that such staff disclosed any past criminal convictions or violations of state and federal law.

15.02.12 The Designated Representative shall have overall responsibility for the operation and compliance of the facility and shall have a minimum of three years verifiable full-time experience in a pharmacy or wholesaler.

15.03.00 Sanitation.

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

15.03.11 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.

15.03.12 The premises shall be free from noxious odors.

15.03.13 There shall be adequate pest control.

15.03.14 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.

15.04.00 Storage.

15.04.10 All drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium such as the USP/NF.

a. If no storage requirements are established for a drug, the drug may be held at “controlled” room temperature, as defined in an official compendium such as USP/NF, to help ensure that its identity, strength, quality, and purity are not adversely affected.

b. Appropriate manual, electromechanical, or electronic temperature and humidity equipment, and/or logs shall be utilized to document proper storage of drugs. Refrigerator and freezer units shall be monitored each business day. If done manually, the temperature shall be recorded each business day. All electromechanical or electronic temperature equipment utilized shall alert the outlet if the temperature falls out of the acceptable range.

c. Packaging of the drugs should be in accordance with an official compendium such as USP/NF and identify any compromise in the integrity of the drugs due to tampering or adverse storage conditions.

d. Controlled substance drugs should be isolated from non-controlled substance drugs and stored in a secure area in accordance with DEA security requirements and standards.

e. All areas of the outlet shall be well lighted and ventilated.

15.04.11 There shall be adequate storage space. Products that are not stored on shelving or under special conditions, such as refrigeration, shall not be stored directly on the floor.

15.04.12 Drugs and devices shall be placed under proper storage conditions as soon as possible after receipt.

15.04.13 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.

15.05.00 Security.

15.05.10

a. All facilities used for wholesale drug distribution shall be secure from unauthorized entry:

(1) Access from outside the premises shall be kept to a minimum and be well-controlled;

(2) The outside perimeter of the premises shall be well-lighted; and

(3) Entry into areas where drugs are held shall be limited to authorized personnel.

b. All facilities shall be equipped with an alarm system 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.

c. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

d. All facilities shall be equipped with inventory management and control systems that detect, protect against, and document any instances of theft, diversion, or counterfeiting.

e. All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

15.05.11 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.

15.05.12 Storage areas shall be constructed in such a manner as to reduce the possibility of illegal entry. 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.

15.05.13 Any theft, suspicious loss, or recurring loss of prescription drugs or any loss of controlled substances shall be reported to the Board within thirty calendar days of the loss, 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.

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

15.06.00 Drug receipt, handling, and shipment.

15.06.10 Drugs and devices shall be placed under proper storage conditions as soon as possible after receipt.

15.06.11 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.

15.06.12 Upon receipt, each shipping container shall be visually examined for identity and to determine if it may contain contaminated, contraband, counterfeit, suspected of being counterfeit or damaged drugs or drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination, adulteration, misbranding, counterfeiting, suspected of being counterfeit, or other damage to the contents.

15.06.13 The drugs found to be unacceptable under section 15.06.12 shall be quarantined from the rest of stock until the examination and determination that the drugs are not outdated, damaged, deteriorated, misbranded, counterfeited, or adulterated and determined to be fit for human use.

15.06.14 Each outgoing shipment shall be carefully inspected for identity of the drugs and to ensure that the drugs for shipment have not been damaged in storage or held under improper conditions.

15.06.15 Upon receipt, a wholesale distributor must review records for the acquisition of drugs for accuracy and completeness, noting the wholesale distributors involved.

15.06.16 The recordkeeping requirement in 15.09.00 shall be followed for all incoming and outgoing drugs and devices.

15.07.00 Returned drugs.

15.07.10 A drug which has been returned to the wholesaler shall be segregated from other stock until it can be determined if the item is salable and suitable for placement into inventory or if it is unsalable.

15.07.11 Any drug or device returned to a manufacturer or wholesale distributor shall be kept under proper conditions for storage, handling, transport, shipment, and documentation showing that proper conditions were maintained prior to its return is provided to the manufacturer or wholesale distributor to which the drugs are returned.

15.07.12 If the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, or returned to the supplier, unless examination, testing or other investigation proves that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity.

15.07.13 Any returned drug which is deemed unsalable shall be handled in accordance with the procedures delineated in regulation 15.08.00.

15.08.00 Unsalable drugs (outdated, damaged, adulterated, misbranded, counterfeit, or suspected of being counterfeit).

15.08.10 Counterfeit drugs are those in which the container, shipping container, seal, or labeling, without authorization, bears the trademark, trade name, or other identifying mark, imprint, device, or any likeness thereof, of a manufacturer, processor, packer, or distributor other than the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by such other manufacturer, processor, packer, or distributor.

15.08.11 A drug or device shall be deemed to be adulterated if:

a. It consists in whole or in part of any filthy, putrid, or decomposed substance; or

b. It has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

c. If the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics which it purports or is represented to possess; or

d. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

e. If it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal food, drug and cosmetic act.

(1) It is a color additive, the intended use of which is for purposes of coloring only, and is unsafe within the meaning of the federal food, drug, and cosmetic act;

(2) If it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of these tests or methods of assay, those prescribed under the authority of the federal food, drug, and cosmetic act. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefore set forth in the compendium, if its difference in strength, quality, or purity from that standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the Homeopathic Pharmacopoeia of the United States and not those of the United States Pharmacopoeia;

(3) If it is not subject to paragraph (2) and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;

(4) If it is a drug and any substance has been (a) mixed or packed therewith so as to reduce its quality or strength; or (b) substituted wholly or partially into it.

15.08.12 A drug or device shall be deemed to be misbranded if the label is false or misleading in any particular; or the label does not bear the name and address of the manufacturer, packer, or distributor, and does not have an accurate statement of the quantities of the active ingredients in case of a drug; or if the label does not show an accurate monograph for legend drugs.

15.08.13 Any unsalable drug shall be segregated in a specific area away from salable stock.

15.08.14 Any drug or device whose immediate or sealed outer or secondary containers or labeling is adulterated, misbranded, counterfeited, or suspect of being counterfeit shall be quarantined and

physically separated from other drugs or devices until it is returned to either the manufacturer or wholesale distributor from which it was acquired or destroyed. When the immediate or sealed outer or secondary containers or labeling of any drug or device is adulterated, misbranded, counterfeited, or suspect of being counterfeit, notice of the adulteration, misbranding, counterfeiting, or suspected counterfeiting shall be provided to the Board, FDA, and manufacturer and wholesale distributor from which it was acquired within three (3) business days.

15.08.15 Any drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, or suspect of being counterfeit, shall be identified as such, and shall be quarantined and physically separated from other drugs or devices until they are returned to the manufacturer or wholesale distributor from which acquired or destroyed.

15.08.16 Contraband, counterfeit, or suspected to be counterfeit drugs and devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and FDA.

15.08.17 The shipping container, immediate or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent shall not be destroyed until its disposition is authorized by the Board and FDA.

15.08.18 An unsalable controlled substance shall be disposed of in compliance with the requirements of the drug enforcement administration and appropriate records shall be kept.

15.08.19 In the case of a drug or a device which is unsalable, records shall be kept which contain the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

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

f. If just an NDC number is used the wholesaler or manufacturer shall maintain a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable for examination by the Board for at least THREE years;

g. Method of disposition of item;

h. Date of disposition; and

i. Method of destruction, if applicable; and

j. Signature of individual destroying, if applicable, and signature of individual witnessing destruction.

15.09.00 Recordkeeping.

15.09.10 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 than 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.

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

a. All such records, including pedigrees, shall be retained for a period of at least three years after the date of any transaction relating to such record or inventory by any process providing an exact duplicate of the original order in a reproducible quality acceptable to the Board. Records shall be retained in a format that cannot be altered.

b. A wholesaler in the possession of a pedigree (a document or electronic file containing information that records each distribution of any given prescription drug that leaves the normal distribution channel) for a prescription drug shall verify that each transaction on the pedigree has occurred prior to distributing the prescription drug.

c. The pedigree shall include all necessary identifying information concerning each sale in the chain of distribution of the product from the manufacturer or first authorized distributor of record through the acquisition and sale by a wholesaler until final sale to a pharmacy or other person dispensing or administering the prescription drug. When a wholesaler distributes a product to another wholesaler, both the distributing and receiving wholesaler shall maintain a copy of the pedigree. The pedigree shall include at least the following:

(1) The name, address, telephone number, and, if available, the e-mail address of each owner of the prescription drug and each wholesaler of the drug;

(2) The name and address of each location from which the prescription drug was shipped, if different from that of the owner;

(3) The transaction dates;

(4) Certification that each recipient has authenticated the pedigree;

(5) The name of the prescription drug;

(6) The dosage form and strength of the prescription drug;

(7) The size and number of containers;

(8) The lot number of the prescription drug; and

(9) The name of the manufacturer of the finished dosage form.

d. Effective January 1, 2017, all wholesalers shall be required to use electronic pedigrees.

Records on an automated data processing system or subsequent storage of such records must be immediately retrievable (via monitor display or hard copy printout).

15.09.12 Retrievability of Records. For the purposes of these regulations, records and inventories shall be deemed “readily retrievable” if they meet the following requirements:

a. The following records shall be maintained on the premises of the registrant at all times and shall be made available for inspection by the Board or its inspectors immediately upon request:

(1) All DEA-222 forms executed during the three years preceding the request;

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

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

(4) List(s) of symbols and codes, if applicable. Symbols and codes may be used to identify any manufacturer, distributor, or repackager. If such symbols and codes appear in the records of the registrant, the registrant shall keep a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable and available for examination by the Board for at least three years.

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

(1) All unexecuted DEA-222 forms.

(2) Specific records requested by the inspector if the inspector determines the records are not maintained in a readily retrievable manner.

(3) Records of receipt of non-controlled prescription drugs.

c. Pedigrees shall be made available to the board or its inspectors within five business days of request.

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

a. Each inventory shall contain a complete and accurate record of all controlled substances (including outdated controlled substances, returns from customers, and items ordered but not yet invoiced) on hand on the date the inventory is taken. The inventory shall be maintained in written, typewritten or printed form at the outlet. Schedule II drugs shall be separated from schedule III, IV, and V drugs. Controlled substances shall be deemed to be “on hand” if they are in the possession of or under the control of the registrant.

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

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

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

e. The following information shall be recorded on the inventory:

(1) The name of the drug;

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

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

(4) The number of commercial containers of each finished form.

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

15.09.14 Receipts.

a. In-state prescription drug wholesalers shall only receive prescription drugs and controlled substances from an entity that is registered by the Colorado State Board of Pharmacy. This section shall not apply to intracompany or reverse distribution transactions.

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

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received if a controlled substance;

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

g. Name of the receiver;

h. Address of the receiver;

i. Name of the distributor that physically distributed the drug directly to the receiver;

j. Address of the distributor where the drug was directly distributed from;

k. DEA registration number of the distributor if a controlled substance;

l. DEA registration number of the receiver if a controlled substance;

m. The DEA form 222 or an electronic order form shall be completed for each schedule ii controlled substance received.

15.09.16 All records of receipt (including credit invoices) of prescription drugs and controlled substances shall be maintained for a period of time not less than two years from the date the drugs were received. Records of receipt (including credit invoices) of non-controlled prescription drugs need not be maintained on the premises provided that they shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors.

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

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

15.09.19 Distribution.

a. A manufacturer or wholesaler as defined in regulation 15.01.00 shall furnish prescription drugs only to a person or entity licensed by the appropriate regulatory board. Before furnishing prescription drugs to a person not known to the wholesaler, the wholesaler shall affirmatively verify that the person or entity is legally authorized to receive the prescription drugs by contacting the appropriate regulatory board.

b. Prescription drugs furnished by a manufacturer or wholesaler shall be delivered only to a practitioner authorized by law to prescribe the drug or to an entity licensed or registered by the Board. In the case of such entities registered or licensed by the Board, drugs shall be distributed only to the registered or licensed address. The manufacturer or wholesaler may furnish prescription drugs to an authorized person or agent of the person listed on the license if the identity and authorization of the recipient is properly established and the method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person or agent.

c. Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving agent signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

15.09.20 Records of distribution of controlled substances and prescription drugs. An outlet which distributes prescription drugs and/or controlled substances shall record the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

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

f. The date of distribution;

g. If just an NDC number is used the wholesaler or manufacturer shall maintain a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable for examination by the Board for at least THREE years;

h. The name and address of the distributing wholesaler;

i. The name and address of the receiver;

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

k. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form or an electronic order.

15.09.21 These records of distribution shall be retained for a period of time not less than two years from the date of the distribution.

15.09.22 Records of distribution may be maintained electronically if the following requirements are met:

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

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

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

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

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

or

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

(3) It is the responsibility of the manager to ensure that all wholesale staff is aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the outlet

manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these regulations.

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

(1) The name of the drug;

(2) The strength of the drug;

(3) The dosage form if appropriate;

(4) The quantity of the drug;

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

(6) The date of distribution;

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

(8) The name and address of the receiver; and

(9) When a controlled substance is distributed, the record shall also indicate the drug enforcement registration number of the distributing outlet and the receiver.

15.09.23 Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion or other loss of any prescription drug or controlled substance to the Board or as required by the Drug Enforcement Administration or other state and/or federal agencies for prescription drugs and controlled substances.

15.09.24 Records detailing losses of prescription drugs and controlled substances shall be maintained on the premises of the registrant and shall be made readily available for inspection by the Board or its inspectors immediately upon request.

15.10.00 Policies and procedures.

15.10.10 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 procedure 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. The registrant shall have 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 returned to the manufacturer or otherwise destroyed, and documented.

c. 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) 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.

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

e. A procedure to ensure that any outdated, misbranded, counterfeit, adulterated or unsalable 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 3 years after dispositions of the outdated drugs.

f. 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.

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

h. Procedures which assure that all prescription drugs and controlled substances are only received from entities that are registered by the Colorado State Board of harmacy. This section shall not apply to intracompany or reverse distribution transactions.

i. A procedure to ensure that drugs are distributed only to individuals or entities with authorization to possess them.

j. A procedure to ensure that drugs are only distributed to practitioners authorized by law to prescribe the drug or to an entity licensed or registered by the Board. In the case of such entities registered or licensed by the Board, drugs shall be distributed only to the registered or licensed address.. In the event the license does not show the address, a written confirmation from the regulatory board licensing or registering the individual or entity shall be obtained.

k. A procedure to ensure verification of all transactions on a pedigree prior to distribution of the drug.

l. A procedure to ensure a pedigree is furnished when distribution occurs outside of the normal distribution channel.

m. A procedure to ensure that staff have disclosed any past criminal convictions or violations of state and federal law.

15.10.11 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 15.02.10.

15.10.12 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.

15.10.13 Additional requirements for wholesalers which distribute veterinary drugs directly to a person responsible for control of an animal.

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

a. A licensed veterinarian has issued, prior to such sale or delivery, a written prescription order for the drug in the course of an existing, valid veterinarian-client-patient relationship;

b. The original order must be retained on the premises of the registrant for two years from the date of the last transaction affecting the order;

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

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

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

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

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

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

(1) Date sold/delivered;

(2) Client and patient name;

(3) Veterinarian name;

(4) Veterinarian's DEA registration if a controlled substance;

(5) Drug sold/delivered;

(6) Quantity drug;

(7) Date of issue of order;

(8) Expiration of order; and

(9) Invoice number.

16.00.00 LIMITED LICENSE.

16.00.10 General Criteria. The Board may issue a limited license to a humane society which is duly

registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation or an animal control agency which is operated by a unit of government for purposes of being authorized to purchase, possess, and administer sodium pentobarbital or sodium pentobarbital in combination with other prescription drugs which are medically recognized for euthanasia, to euthanize injured, sick, homeless, or unwanted pets and animals. Such facilities may also purchase, possess, and administer drugs commonly used for the chemical capture of animals for control purposes or to sedate or immobilize pet animals immediately prior to euthanasia.

a. All drugs utilized by the limited license registrant shall be obtained from an individual or entity registered by the Colorado State Board of Pharmacy.

16.00.20 Application Procedure.

a. Original Application.

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

b. Limited License Relocation

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

c. Change of Name of Limited License.

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

d. Reinstatement of Limited License.

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

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

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

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 transfer 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)(I) 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 CRS 12-22-604(3).

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 CRS 24-72-203 and CRS 24-4-104.

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 term of any contract between the licensee and the REC shall be determined by the REC unless superseded by Board order. 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 CRS 12-22-125.2 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 CRS 12-22-125 or CRS 12-22-126, 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 CRS 12-22-125

and/or CRS 12-22-126, 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 CRS 12-22-125 and/or CRS 12-22-126, 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.

19.00.00 ADMINISTRATION.

19.01.00 Immunizations.

19.01.10 Qualifications.

a. A pharmacist, or pharmacy intern under the supervision of a pharmacist certified in immunization, may administer vaccines per authorization of a physician. A copy of the authorization will be maintained at the prescription drug outlet. Routine childhood immunizations, as defined by the Colorado State Board of Health, shall comply with CDC guidelines.

b. Licensees may administer vaccines to a person only if:

(1) The pharmacist or pharmacy intern has completed a pharmacy-based immunization delivery course accredited by the Accreditation Council for Pharmacy Education (“ACPE”) for at least 12 hours of didactic training and at least 8 hours of live hands-on training. Proof of completion of this training shall be posted at the pharmacist’s or pharmacy intern’s main practice location(s).

(2) The pharmacist or pharmacy intern holds a current basic cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or a basic cardiac life support certification. Proof of certification shall be available at pharmacist’s main practice location.

(3) The vaccines are administered in accordance with CDC guidelines.

(4) The prescription drug outlet shall have a current version available, either in hard copy or electronically available, of the CDC reference “Epidemiology and Prevention of Vaccine-Preventable Diseases” .

19.01.20 A trained pharmacist may delegate the administration of vaccines only to a trained pharmacy intern.

19.01.30 Policies and Procedures

a. Prior to administering vaccines or immunizations, pharmacists and pharmacy interns must be trained in a pharmacy-based immunization delivery course accredited as detailed in regulation 19.01.10(b).

b. The prescription drug outlet must maintain and follow written policies and procedures for handling and disposal of used and contaminated equipment and supplies. The prescription drug outlet must obtain a physician protocol for addressing allergic reactions to immunizations.

c. The prescription drug outlet must give the appropriate "Vaccine Information Statement" (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative has received and signed the informed consent form and has had their questions answered prior to the administration of the vaccine.

d. The prescription drug outlet must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

19.01.40 Recordkeeping.

a. The following information must be maintained by the prescription drug outlet for three years for each dose of vaccine administered:

(1) The name, address, and date of birth of the patient;

(2) Patient responses to screening questions for indications/contraindications to the vaccine being administered;

(3) The date of the administration and site of injection of the vaccine;

(4) The name, dose, manufacturer, lot number, and expiration date of the vaccine or immunization;

(5) The name and address of the patient's primary health care provider as identified by the patient;

(6) The name or identifiable initials of the administering pharmacist. If the administration is by a pharmacy intern, the initials of both the intern and supervising pharmacist;

(7) The signed informed consent document for each administration;

(8) Which vaccine information statement was provided; and

(9) The date the VIS was provided.

b. The above records shall be maintained separately from other records of the prescription drug outlet.

20.00.00 CENTRAL PRESCRIPTION PROCESSING

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

authorizations.

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

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

20.00.31 "Fulfillment pharmacy" means the pharmacy where fulfillment occurs.

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

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

20.00.60 Operational Standards.

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

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

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

3. Are registered with the Colorado State Board of Pharmacy as either prescription drug outlets or non-resident prescription drug outlets, depending on the pharmacy's location. All pharmacies participating in the central prescription processing contract must be located within the United States.

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

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

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

20.00.70 Notification to Patients.

a. Prior to the outsourcing of any portion of the dispensing process to another pharmacy, a pharmacy shall:

1. Notify patients that their prescription may be outsourced to another pharmacy; and

2. Give the name of that pharmacy or if the pharmacy is part of a network of pharmacies under common ownership and any of the network pharmacies may dispense the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.

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

20.00.80 Prescription Labeling.

a. Prescriptions shall be labeled with all information required by CRS 12-22-123. In addition, the following shall be included on the label of any prescription dispensed via central processing:

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

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

20.00.90 Responsibilities of Originating Pharmacy.

a. The originating pharmacy, when transmitting a controlled substance order to a contracted pharmacy, shall write “Central Fill” on the face of the original order and record the following:

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

2. The DEA registration of the pharmacy if a controlled substance order;

3. Name of pharmacist transmitting the order; and

4. The date of transmission.

b. The originating pharmacy, when transmitting a non-controlled substance order to a contracted pharmacy, shall maintain records of the following:

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

2. Name of pharmacist transmitting the order; and

3. The date of transmission.

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

1. Date of receipt;

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

3. Name of pharmacy employee accepting delivery.

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

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

20.01.00 Responsibilities of Fulfillment Pharmacy.

a. The fulfillment pharmacy shall:

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

2. Retain a record detailing the following:

i) Date the transmitted order was received;

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

iii) Date the order was fulfilled;

iv) Date prescription delivered to the originating pharmacy; and

v) The method of delivery.

20.01.10 Records.

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

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

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

20.01.20 Policies and Procedures.

a. A policy and procedure manual as it relates to central prescription processing shall be maintained and complied with at all pharmacies involved in the dispensing of the prescriptions. This policy and procedure manual shall be readily available for inspection. The manual shall:

1. Outline the responsibilities of each involved pharmacy;

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

3. Include policies and procedures for:

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

ii) Protecting the confidentiality and integrity of patient information;

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

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

v). Complying with federal and state laws and regulations;

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

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

21.00.00 COMPOUNDING.

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

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

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

21.00.10 Limitations.

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

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

21.00.20 Casual Sales/Distribution of Compounded Products.

a. A prescription drug outlet may only distribute a compounded product to a practitioner authorized by law to prescribe the drug for the purposes of administration. A compounding prescription drug outlet registered pursuant to CRS 12-22-120(9) may distribute compounded product pursuant to CRS 12-22-121(18)(a) and (b)(I) and (II).

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

(1) Verification of practitioner's license or prescription drug outlet's registration from the jurisdiction in which licensed;

(2) Verification of practitioner's or prescription drug outlet's current DEA registration, if controlled substances are distributed to the practitioner;

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

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

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

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

d. Records of distribution shall comply with Regulation 11.07.10 or 11.07.20, whichever is applicable.

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

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

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

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

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

e. Compounding:

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

(a) Formulated for use on or for the patient as the result of a practitioner's prescription drug order, chart order, or initiative, based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice; or

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

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

(2) Compounding does not include the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a significant difference between the compounded drug and the comparable commercially available drug product as determined, by the prescriber, as

necessary for the medical best interest of the patient are not copies of commercially available products. “Significant differences” may include, but are not limited to, the removal of a dye for medical reasons (such as allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a “significant” difference to justify compounding.

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

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

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

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

j. SOPS: Standard operating procedures.

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

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

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

21.10.00 Compounding of Non-Sterile Products.

21.10.10 Policy and Procedure Manual.

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

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

(1) Responsibility of compounding personnel;

(2) Verification of compounding accuracy;

(3) Personnel training and evaluation in compounding skills;

(4) Environmental quality and control;

(5) Labeling and recordkeeping;

(6) Finished preparation release check;

(7) Quality control procedures, as appropriate;

(8) Storage and beyond-use dating;

(9) Adverse event reporting and recalls; and

(10) Quality assurance program.

21.10.20 Personnel Education, Training and Evaluation.

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

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

21.10.30 Environmental Quality and Controls.

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

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

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

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

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

f. Compounding areas shall be maintained in a clean and sanitary condition. Adequate washing facilities are to be provided, including hot and cold running water, soap or detergent, and air driers or single-service towels.

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

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

21.10.40 Equipment.

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

b. Equipment shall be of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to

alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result.

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

d. Written procedures outlining required equipment, calibration, appropriate maintenance, monitoring for proper function, controlled procedures for use of the equipment and specified time frames for these activities shall be established and followed. Results of equipment calibration and appropriate maintenance reports shall be kept on file at the outlet for at least two years from the report date. These results shall be available for inspection.

21.10.60 Components.

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

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

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

(1) Chemically Pure (CP);

(2) Analytical Reagent (AR); or

(3) American Chemical Society (ACS); or

(4) Food Chemical Codex.

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

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

f. Drug preparations that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.

g. Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from Regulation 21.10.60 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of CRS 12-22-128(2).

21.10.70 Finished Preparation Release Checks.

a. Physical Inspection

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

b. Compounding Accuracy Checks

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

(a) Verification of label for accuracy; and

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

21.10.80 Storage and Beyond-Use Dating.

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

b. In the absence of stability information that is applicable to a specific drug and preparation, the following maximum beyond-use dates are to be used for non-sterile compounded preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature unless otherwise indicated.

(1) For non-aqueous liquids and solid formulations

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

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

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

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

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

21.10.90 Formulation Record.

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

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

(2) All ingredients and their quantities;

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

(4) The beyond-use date;

(5) The containers used in dispensing;

(6) Storage requirements; and

(7) Procedures for quality control, if applicable.

21.11.00 Compounding Record.

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

(1) Name and strength of the compounded preparation;

(2) Formulation record reference for the preparation;

(3) Sources and lot numbers of each ingredient;

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

(5) Total number of dosage units compounded;

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

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

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

(9) Date prepared;

(10) Beyond use date;

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

(12) Results of quality control procedures, if applicable.

21.11.10 Labeling of Non-Sterile Compounded Preparations.

a. Labeling of non-sterile compounded products dispensed pursuant to a prescription order or

LTCF chart order shall include at least the following:

(1) All requirements of CRS 12-22-123;

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

(3) Beyond-use date;

(4) Storage directions when appropriate; and

(5) “This product was compounded by the pharmacy” .

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

(1) All requirements of CRS 12-22-123;

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

(3) Beyond-use date; and

(4) Storage directions, when appropriate.

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

(1) Name and address of the outlet;

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

(3) Total quantity in package;

(4) Beyond-use date;

(5) Batch (lot) number;

(6) Specific route of administration;

(7) Storage directions, when appropriate;

(8) “Rx only” ; and

(9) “This product was compounded by the pharmacy” .

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

(1) Name of the outlet;

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

(3) Total quantity in package;

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

(5) Beyond-use date;

(6) Batch (lot) number;

(7) Specific route of administration; and

(8) Storage directions, if appropriate.

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

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

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

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

d. If a compounded preparation is believed to be defective in any way, the outlet shall immediately recall any product dispensed or distributed. Any product remaining in the outlet shall be immediately quarantined and shall not be dispensed or distributed. Recall records shall include at least the following:

(1) Product name, strength, dosage form;

(2) Reason for recall;

(3) Amount of product made;

(4) Date made; and

(5) Amount of product dispensed or distributed.

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

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

21.20.00 Compounding of Sterile Products (CSPs).

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

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

b. Aseptic Processing: A mode of processing pharmaceutical and medical products that involves

the separate sterilization of the product and of the packaging and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.

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

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

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

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

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

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

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

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

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

solutions, intravenous solutions and ophthalmic preparations.

l. Critical Area: An ISO Class 5 environment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

aa. Sterilizing Grade Filter Membranes: Filter membranes that are documented to retain 100% of a culture of 107 microorganisms of a strain of Brevundimonas (Pseudomonas) diminuta per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22 or 0.2 micrometer porosity, depending on the manufacturer's practice.

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

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

dd. Temperatures:

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

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

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

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

or testing area.

21.20.20 Definitions of Sterile Compounded Products by Risk Level.

a. Low Risk CSPs;

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

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

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

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

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

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

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

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

(e) Personnel shall follow garbing and cleaning requirements.

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

(1) Multiple individual or small doses of sterile products are combined or pooled to

prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions; or

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

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

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

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

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

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

(4) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

21.20.23 Single-Dose and Multiple-Dose Containers.

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

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

21.20.25 Radiopharmaceuticals as CSPs.

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

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

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

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

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

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

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

21.20.30 Policy and Procedure Manual.

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

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

(1) Responsibility of compounding personnel;

(2) Verification of compounding accuracy and sterilization;

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

(4) Environmental quality and control;

(5) Aseptic processing;

(6) Labeling and recordkeeping;

(7) Finished preparation release check;

(8) Storage and beyond-use dating;

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

(10) Patient or caregiver training;

(11) Adverse event reporting and recalls;

(12) Quality assurance program; and

(13) Quality control procedures, as appropriate.

21.20.40 Personnel Education and Training.

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

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

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

(1) Aseptic processing;

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

(3) Sterilization; and

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

21.20.50 Personnel Evaluation in Aseptic Manipulation Skills.

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

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

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

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

21.20.60 Environmental Quality and Controls.

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

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

c. The surfaces of the ceiling, walls, floor, fixtures, shelving, counters, and cabinets in the buffer

area or clean room shall be smooth, impervious, free from cracks and crevices and non-shedding. Junctures of ceilings to walls shall be coved or caulked. There shall be no sink or floor drains in the buffer area or clean room.

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

21.20.70 Environmental Monitoring.

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

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

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

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

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

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

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

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

f. A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the clean room and anteroom and the anteroom and the general pharmacy area. The results shall be reviewed and documented on a daily basis. The

pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 pa (0.02-inch water column, w.c.).

21.20.80 Cleaning and Disinfecting the Workspaces.

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

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

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

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

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

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

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

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

21.20.90 Personnel Cleansing and Garbing.

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

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

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

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

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

f. For high risk: If personnel leave the buffer area, they must don new hair covers, masks, shoe

covers, gowns and gloves prior to reentry.

21.21.10 Components.

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

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

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

(1) Chemically Pure (CP);

(2) Analytical Reagent (AR); or

(3) American Chemical Society (ACS); or

(4) Food Chemical Codex.

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

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

f. Drug preparations that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.

g. Sterile ingredients and components:

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

h. Non-sterile ingredients and components:

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

(2) If non-USP or non-NF active ingredients, added substances, or excipients are utilized, a certificate of analysis from the supplier of the ingredient shall be

maintained at the prescription drug outlet for at least two from the date of preparation.

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

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

i. Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from regulation 21.21.10 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of CRS 12-22-128(2).

21.21.20 Equipment.

a. Written procedures outlining required equipment, calibration, appropriate maintenance, monitoring for proper function, controlled procedures for use of the equipment and specified time frames for these activities shall be established and followed. Results of equipment calibration and appropriate maintenance reports shall be kept on file at the outlet for at least two years from the report date and shall be available for inspection.

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

21.21.30 Finished Preparation Release Checks and Tests.

a. Physical Inspection

(1) Finished CSPs shall be individually inspected after compounding pursuant to written procedures. Immediately after compounding, and prior to dispensing or distribution, each product shall be inspected for evidence of particulates or other foreign matter, container-closure integrity, precipitation, cloudiness, and any other apparent visual defect. Defective product shall be segregated from other product and shall not be dispensed or distributed.

b. Compounding Accuracy Checks.

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

(a) Verification of label for accuracy;

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

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

were obtained.

c. Sterility Testing.

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

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

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

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

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

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

(3) When a high risk CSP is dispensed or distributed before receiving the results of the sterility test, there shall be a written procedure requiring daily observation of the incubating test specimens and requiring an immediate recall if there is any evidence of microbial growth. In addition, the patient and the practitioner of the patient to whom a potentially contaminated CSP was administered shall be notified of the potential risk. Positive sterility results shall prompt a rapid and systematic investigation of aseptic technique, environmental and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

d. Bacterial Endotoxin (Pyrogen) Testing.

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

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

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

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

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

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

21.21.40 Storage and Beyond-Use Dating.

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

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

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

(1) Low risk CSPs with greater than 12-hour BUD:

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

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

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

(3) Medium risk CSPs:

Room temperature:	No more than 30 hours
Refrigerated temperature:	No more than 9 days
Frozen:	No more than 45 days

(4) High risk CSPs:

Room temperature:	No more than 24 hours
Refrigerated temperature:	No more than 3 days
Frozen:	No more than 45 days

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

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

21.21.50 Formulation Record.

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

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

(2) All ingredients and their quantities;

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

(4) The beyond use date;

(5) The containers used in dispensing;

(6) Storage requirements; and

(7) Procedures for quality control, if applicable.

21.21.60 Compounding Record.

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

(1) Name and strength of the compounded preparation;

(2) Formulation record reference for the preparation;

(3) Sources and lot number of each ingredient;

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

(5) Total number of dosage units compounded;

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

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

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

(9) Date of preparation;

(10) Beyond use date;

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

(12) Results of quality control procedures; and

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

21.21.70 Labeling of CSPs.

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

(1) All requirements of CRS 12-22-123;

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

(3) Beyond-use date;

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

(a) Name of base solution; and

(b) name and amounts of drugs added.

(5) Storage directions; and

(6) “This product was compounded by the pharmacy.”

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

(1) All requirements of CRS 12-22-123;

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

(3) Beyond-use date;

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

(a) Name of base solution; and

(b) Name and amounts of drugs added; and

(5) Storage directions.

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

(1) Name of the outlet;

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

(3) Total quantity in package;

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

(5) Beyond-use date;

(6) Batch (lot) number;

(7) Specific route of administration;

(8) Storage directions;

(9) “Rx only” ; and

(10) “This product was compounded by the pharmacy.”

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

(1) Name of the outlet;

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

(3) Total quantity in package;

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

(5) Beyond-use date;

(6) Batch (lot) number;

(7) Specific route of administration; and

(8) Storage directions.

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

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

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

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

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

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

d. If a CSP is believed to be defective in any way, the outlet shall immediately recall any product dispensed or distributed. Any product remaining in the outlet shall be immediately quarantined and shall not be dispensed or distributed. Recall records shall include at least the following:

(1) Product name, strength, dosage form;

(2) Reason for recall;

(3) Amount of product made;

(4) Date made; and

(5) Amount of product dispensed or distributed.

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

f. Adverse event reports and product recall records shall be retained and be available for

inspection at the outlet for at least two years.

21.22.00 Quality Assurance Program.

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

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

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

(2) Describe specific monitoring and evaluation activities;

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

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

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

21.22.10 Cytotoxic Drug Preparation.

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

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

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

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

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

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

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

a. Pharmacists and pharmacies or other outlets where sterile compounding is provided may be exempt from this rule when compounding is restricted to utilizing compounds or products that are contained only in a closed or sealed system and can be transferred or

compounded within this self-contained system or topical products that require further transfer or combination in order to achieve a finished product without further modification of the product.

22.00.00 Initial Decisions [Eff. 03/02/2009]

22.00.10 Written form, service, time, and filing requirements.

a. All designations of record, requests, motions, exceptions, and any responses thereto (hereinafter "pleading" or pleadings") must be in written form, mailed with a certificate of mailing to the board and the opposing party.

b. In the event that an electronic filing system is implemented in the Division of Registrations for the receipt of pleadings, the items listed in this paragraph may be submitted in electronic form with a certificate of filing to the board and the opposing party.

c. All pleadings must be received by the board by 5:00 pm on the date the filing is due. These rules do not provide for any additional time service by mail.

d. All pleadings must be filed with the board and not with the Office of Administrative Courts. Any pleading filed in error with the Office of Administrative courts will not be considered.

22.00.20 Authority to review.

a. The board hereby initiates a review of all initial decisions on its own motion pursuant to § 24-4-105(14)(a)(ii), C.R.S. without requiring a vote for each case.

b. This option to review shall apply regardless of whether a party files exceptions to the initial decision.

22.00.30 Designation of record and transcripts.

a. Any party seeking to reverse or modify the initial decision of the administrative law judge shall file with the Board a designation of the relevant parts of the record for review ("Designation of Record"). Designations of record are due and must be received by the board within twenty days of the date on which the Board mails the initial decision to the parties' address of record with the Board.

b. In the absence of a designation of record, the record for the purposes of the board's review of the initial decision as set forth in section 24-4-105(14)(a) shall in all cases include the following:

(1) All pleadings filed with the office of administrative courts or applicable hearing tribunal;

(2) All applications presented or considered during the hearing;

(3) All documentary or other exhibits admitted into evidence at the hearing;

(4) All documentary or other exhibits presented or considered during the hearing;

(5) All matters officially noticed during the hearing; and

(6) Any findings of fact and conclusions of law proposed by any party at the hearing.

c. Transcripts: Transcripts shall not be deemed part of a designation of record unless specifically identified, ordered, and timely filed. To designate a transcript or portion thereof, the following procedures apply:

(1) The designation of record must identify with specificity the transcript or portion thereof to be transcribed. For example, a party may designate the entire transcript, testimony of particular witness(es), a legal ruling or argument,, or other information necessary to identify the portion of the transcript to be transcribed.

(2) Any party who includes a transcript or a portion thereof as part of the designation of record must order the transcript or relevant portions by the date on which the designation of record is due. as noted above, a designation of record is due within twenty days of the date on which the Board mails the initial decision to the parties.

(3) When ordering the transcript, the ordering party shall request the court reporter to complete and provide the board the transcript and one copy of the transcript within thirty days and shall timely pay all fees associated with such a request.

(4) If a party designates a portion of the transcript, the opposing party may also file a supplemental Designation of Record identifying, additional portions of the transcript. This supplemental designation of record is due and must be received by the board within ten days after the date on which the original designation of record was due and received by the board.

(5) An party filing a supplemental designation of record shall request the court reporter to complete and provide the board the supplemental transcript and one copy of the supplemental transcript within thirty days of the supplemental designation of record and shall timely pay all fees associated with such a request.

(6) Transcripts that are ordered by either party and not provided to the Board in a timely manner by the court reporter due to non-payment, insufficient payment or failure to request as set forth above will not be considered by the Board.

22.00.40 Filing of exceptions and responsive pleadings

a. Any party wishing to file exceptions shall adhere to the following timelines:

(1) If no transcripts are ordered, exceptions are due within thirty days from the date on which the Board mails the initial decision to the parties. Both parties' exceptions are due on the same date.

(2) If transcripts are ordered by either party, the following procedure shall apply. Upon timely receipt of all transcripts identified in the designations of record, the Board shall mail notification to the parties stating that the transcripts have been received. Exceptions are due within thirty days from the date on which such notification is mailed. Both parties' exceptions are due on the same date.

b. Either party may file a responsive pleading to the other party's exceptions. All responsive pleadings shall be due and received by the board within 10 days of the date on which the exceptions were due. No other pleadings will be considered except for good cause shown.

c. The Board may in its sole discretion, upon a showing of good cause, grant an extension of time to provide a designation of record, exceptions, or responsive pleadings, or may

delegate the discretion to grant such an extension of time to the board's program director.

22.00.50 Request for oral argument

a. All requests for oral argument must be in writing and filed by the deadline for responsive pleadings. Requests received by the board after this time will not be considered.

b. It is within the sole discretion of the Board to grant or deny a request for oral argument. If oral argument is granted, both parties shall have the opportunity to participate.

c. Each side shall be permitted five minutes for oral argument unless such time is extended by the Board or its Program Director.

23.00.00 ELECTRONIC PRESCRIPTION DRUG MONITORING PROGRAM

23.00.10 Definitions:

a. "Prescription Drug Outlet" means any resident or nonresident pharmacy registered with the Colorado State Board of Pharmacy.

b. "PDMP" means the Electronic Prescription Drug Monitoring Program.

23.00.20 Submission Requirement.

All prescription drug outlets shall submit their controlled substance dispensing transactions for Schedule II, III, IV, and V Controlled Substances to the PDMP with the exception of the following:

a. Hospitals licensed or certified pursuant to CRS 25-1.5-103 that dispense no more than a 24-hour supply of a controlled substance to an outpatient; or

b. Hospitals licensed or certified pursuant to CRS 25-1.5-103 which dispense controlled substances only pursuant to chart orders; or

c. A prescription drug outlet which has applied to the Board and received a waiver from the Prescription Controlled Substance Abuse Monitoring Advisory Committee. Waivers will only be considered if the pharmacy has no electronic automation.

23.00.30 Data Submission Timeline.

Every prescription drug outlet must ensure controlled substance dispensing transactions are reported to the PDMP twice each month on the following schedule:

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

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

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

23.00.40 Data Submission Format.

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

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

b Bin (Bank Identification Number);

c Version Number (a number to identify the format of the transaction sent or received);

d. Transaction Code;

e. NABP or DEA number assigned to pharmacy;

f. Customer ID (number to identify the patient receiving the RX);

g. Zip Code (3 digit US Postal Code identifying the State Code), if applicable;

h. Customer's Birth Date;

i. Sex Code;

j. Date Filled;

k. Prescription Number;

l. New/Refill Number;

m. Metric Quantity;

n. Days Supply;

o. Compound Code;

p. NDC Number of the drug dispensed;

q. Prescriber's DEA registration;

r. DEA suffix, if applicable;

s. Date RX Written;

t. Number of Refills Authorized;

u. RX Origin Code;

v. Customer Location;

w. Diagnosis Code, if available;

x. Alternate Prescriber #, if applicable;

y. Patient Last Name;

z. Patient First Name;

aa. Patient Street Address;

bb. Patient's state of residence;

cc. Patient's zip code;

dd. Triplicate Serial Number, if appropriate; and

ee. Filler Field to be populated with Payment Type as designated by PDMP vendor.

23.00.50 Data Correction.

a. Any errors identified by the PDMP shall be corrected and resubmitted by the prescription drug outlet on the following schedule:

1. For dispensing transactions from the 1st through the 15th day of each month, errors shall be corrected no later than the first day of the following month.

2. For dispensing transactions from the 16th through the 31st of each month, errors shall be corrected no later than the 16th day of the following month.

b. If errors cannot be corrected, the pharmacy must retain a record in written format detailing the following information for each uncorrected error:

1. Detail of Error Notification highlighting uncorrected error(s); and

2. Detailed reason of why error cannot be corrected.

Editor's Notes

History

Rules 2.01.10; 2.01.30; 3.00.50; 6.00.20; 6.00.30; 6.00.40; 8.00.10; 11.04.20; 14.03.10 eff. 7/30/2007.

Rules 8.00.10; 11.04.10; 20.00.00 eff. 9/30/2007.

Rule 4.00.00 eff. 11/30/2007.

Rules 3.01.20, 10.00.00 eff. 03/01/2008.

Rules 5.01.31; 15.01.11; 15.01.12; 15.09.11; 15.09.14; 22.00.00 eff. 5/30/2008.

Rules 4.02.00 (c), 21.00.00, 23.00.00 eff. 06/30/2008.

Rules 1.00.00, 2.00.00, 3.00.00, 5.00.00, 7.00.00, 11.00.00, 12.00.00, 14.00.00 eff. 11/30/2008.

Rule 15.09.11 eff. 01/31/2009.

Rules 6.00.30, 11.06.00, 22.00.00 eff. 03/02/2009.

Rule 9.00.00 eff. 04/30/2009.

Rules 5.00.55, 5.01.31(a), 6.00.20(f), 14.00.40, 15.01.17, 15.01.18, 15.08.19(f), 15.09.11(d), 15. 09.15, 15.09.19, 15.09.20(g-h), 15.09.23, 15.09.24, 15.10.10, 16.00.20(d), 19.01.10(b), 19.01.30(a) eff. 12/30/2009.