**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 drugs dispensed or active ingredients used in compounded preparations 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).

**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):

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

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

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

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

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

2.01.20 Additional Information. The following shall also appear on the prescription 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 or license number of the pharmacist making the final evaluation. This information shall be maintained and available for inspection for a period of two years from the date of any transaction relating to the order unless otherwise required by statute.

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

authority to refill shall be issued in a written copy.

2.01.50 Transfer of Prescription Orders Between Prescription Drug Outlets.

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

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

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

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

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

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

d. The one-time transfer of original prescription information for a controlled substance listed in schedules III, IV, or V for the purpose of dispensing is permissible between pharmacies. However, pharmacies electronically sharing a real-time, on-line 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 Final Evaluation. Each time a prescription drug or device is dispensed in a prescription drug outlet, a pharmacist shall make the final evaluation of the transaction. At the time of such final evaluation, the pharmacist shall take whatever action is necessary to ensure that the initial interpretation, container, label, and prescription drug or device dispensed, as well as all records relating to the transaction are complete, accurate, and appropriate.

a. The record or records of each dispensing transaction shall bear the identity of the pharmacist making the final evaluation, and this pharmacist shall be held responsible and accountable for each dispensing transaction which bears this pharmacist’s identity.

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

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

3.00.70 Responsibility for Unlicensed Assistants. A pharmacist:

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

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

3.00.80 Return or Exchange of Drugs for Dispensing 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:

a. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of (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 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.

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;

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.

3.02.00 Compounding.

The purpose of this regulation is to provide information to pharmacists to enhance the pharmacist's ability to compound preparations that are of acceptable strength, quality and purity.

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

3.02.10 Limitations.

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.

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

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

b. All ingredients and their quantities;

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

d. The formulation assigned expiration date;

e. The container used in dispensing;

f. The storage requirements;

g. Procedures for quality control.

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

a. The name and strength of the compounded preparation;

b. The formulation record reference for the preparation;

c. The sources and lot numbers of each ingredient;

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

e. The total number of dosage units compounded;

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

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

h. The date of preparation;

i. The assigned internal identification number if applicable;

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

(1) For nonaqueous and solid formulations

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

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

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

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

k. The prescription number, if appropriate;

l. The results of quality control procedures.

3.02.40 Labeling of Dispensed Compounded Prescriptions.

a. Labeling shall comply with CRS 12-22-123. In addition, the label shall contain the beyond-use expiration date of the product.

3.02.50 Casual Sales/distribution of Compounded Products.

a. A pharmacy may only distribute a compounded product to a practitioner authorized by law to prescribe the drug.

b. The pharmacy must retain the following information on a current basis for each practitioner to whom it distributes compounded products:

1. Verification of practitioner's license from the jurisdiction in which licensed;

2. Verification of practitioner'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 practitioners 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 DEA as an exporter.

c. Labeling of compounded products which are distributed shall contain at least the following:

1. Name and address 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" ;

10. “This product was compounded by the pharmacy.

d. Records of distribution shall comply with regulation 11.07.20.

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. *[Eff 10/01/2006]*

3.04.10 A prescription drug outlet may accept donations of non-controlled cancer drugs and medical devices from cancer patients or the cancer patient's family, provided the drugs or devices meet the following requirements: *[Eff 10/01/2006]*

a. The drug 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; *[Eff 10/01/2006]*

b. The drug is not expired; *[Eff 10/01/2006]*

c. The drug is not adulterated or misbranded as determined by the pharmacist; *[Eff 10/01/2006]*

d. The drug does not require refrigeration, freezing, or other special temperature requirements beyond controlled room temperature; and *[Eff 10/01/2006]*

e. The drug does not require patient registration with the drug manufacturer prior to dispensing. *[Eff 10/01/2006]*

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 to eligible patients based on a valid order from a practitioner. An eligible patient is defined as an uninsured or underinsured cancer patient who meets the eligibility criteria established in rule by the State Board of Health. The pharmacy may only charge a handling fee for such dispensing. This fee shall be determined by the State Board of Health. *[Eff 10/01/2006]*

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: *[Eff 10/01/2006]*

a. Name and address of person donating the drug or device; *[Eff 10/01/2006]*

b. Drug name and strength; *[Eff 10/01/2006]*

c. Manufacturer of drug or device; *[Eff 10/01/2006]*

d. Manufacturer's lot number; *[Eff 10/01/2006]*

e. Drug expiration date; *[Eff 10/01/2006]*

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

g. Quantity received. *[Eff 10/01/2006]*

3.04.43 Records or distribution shall include at least the following: *[Eff 10/01/2006]*

a. Name and address of medical clinic or prescription drug outlet; *[Eff 10/01/2006]*

b. Drug or device name; *[Eff 10/01/2006]*

c. Drug strength; *[Eff 10/01/2006]*

d. Dosage form, if appropriate; *[Eff 10/01/2006]*

e. Quantity distributed; *[Eff 10/01/2006]*

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

g. Manufacturer's lot number; *[Eff 10/01/2006]*

h. Drug expiration date; *[Eff 10/01/2006]*

i. Date of distribution; and *[Eff 10/01/2006]*

j. Name and address of distributing pharmacy. *[Eff 10/01/2006]*

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

d. Score Transfer applicants must complete their licensure within one year from the date the

score transfers are received by the Colorado State Board of Pharmacy.

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

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

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

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 of Pharmacist License. A person seeking to reinstate his/her license as a pharmacist shall be required to pay the appropriate fee and prove 24 hours continuing education in the 24-month period preceding the application date. If the person's pharmacist license has been lapsed for over two years, such person shall be required to take and pass the approved examinations as specified below prior to the granting of such reinstatement:

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

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

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

4.05.00 License Changes.

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

b. Change of employment or address. All pharmacists 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.**

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

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

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

5.01.00 Prescription Drug Outlet.

5.01.10 Controlled Substance Inventory.

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

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

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

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

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

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

d. Upon incorporation of an existing prescription drug outlet.

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

5.01.30 For the purposes of this regulation 5.00.00:

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

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

5.01.31 Within every prescription drug outlet as defined in CRS 12-22-102(30.2), there shall be one area designated as the principal compounding/dispensing area. In addition to the principal compounding/dispensing area there may be one or more satellite compounding/dispensing areas (“satellites” ) which are located in the same building as the principal compounding/dispensing area. The principal compounding/dispensing area and any satellite shall comply with the following conditions: *[Eff 10/01/2006]*

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

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

c. 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. *[Eff 10/01/2006]*

(1) The free floor space behind all compounding/dispensing counters or work surfaces shall be not less than 30 inches in width; *[Eff 10/01/2006]*

(2) The free floor space between shelf sections shall be not less than 24 inches; *[Eff 10/01/2006]*

(3) There shall be sufficient shelf, drawer and/or cabinet space for proper storage of prescription drugs and devices. *[Eff 10/01/2006]*

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

are or will be performed therein.

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

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

(2) Spatula.

(3) Ointment slab or ointment pads.

(4) Glassine papers for weighing and compounding.

(5) Suitable containers for various dosage forms.

(6) Prescription balance meeting minimum compendia sensitivity.

(7) Weights: appropriate metric.

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

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

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

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

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

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

(4) The current edition of 21 Code of Federal Regulations (“CFR” ) Part 1300 to End containing Drug Enforcement Administration rules relating to controlled substances;

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

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

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

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

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

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

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

a. Minimum Requirements:

(1) The prescription drug outlet shall have a designated area for a laminar flow hood, or it shall have a class 100 clean room as required by General Services Administration Federal Standard 209(b) as amended, for the preparation of sterile products. If a clean room is installed and utilized, the clean room shall;

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

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

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

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

(2) Equipment:

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

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

(c) Supplies necessary for sterile product compounding;

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

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

(a) Guide to Parenteral Admixtures or Handbook on Injectable Drugs or other

comparable references as determined by the pharmacist manager.

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

b. Other Requirements/Quality Assurance:

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

(a) Name of base solution;

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

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

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

(a) Security.

(b) Sanitation.

(c) Drug storage.

(d) Drug delivery.

(e) Drug labeling.

(f) Drug destruction and returns.

(g) Recordkeeping.

(h) Recall procedures.

(i) Duties of the staff.

(j) Sterile compounding techniques.

(k) Patient training.

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

c. Cytotoxic Drugs: if cytotoxic drugs are prepared:

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

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

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

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

5.01.40 Minimum Hours of Operation.

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

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

5.01.41 Discontinuance.

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

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

c. Upon the discontinuance of the practice of pharmacy in any prescription 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.

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

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

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

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

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

d. 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.

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. Any pharmacist wishing to engage in or engaging in drug therapy management must file a copy of the written agreement between the physician and the pharmacist with the Board. Pharmacists conducting such therapy in inpatient settings or group model integrated closed HMO's must also notify the Board, on a form developed by the Board, that they are practicing drug therapy management, and provide a copy of their general authorization plan as required by 6.00.40.

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 practice residency accredited by the American Society of Health Systems Pharmacists or the American Pharmaceutical Association; or

2. A bachelor of pharmacy degree and 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. A Doctor of Pharmacy degree and 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 in Pharmacotherapy from the Board of Pharmaceutical Specialties, or current certification from the National Institute for Standards in Pharmacist Credentialing. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management.

5. 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. 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.

6.00.80 Insurance.

a . [Expired 05/15/06]

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 PHARMACY MANAGER RESPONSIBILITIES.**

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

a. Diversion of substances from the pharmacy.

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

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

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

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

7.00.20 Administrative Reporting Responsibilities:

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

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

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

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

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

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

chart order dispensing.

g. It is the responsibility of the pharmacist manager to ensure that all prescription drug outlet staff are aware that they must be able to print a report of all prescription order or chart order transactions for such period of time as the Board or its inspector(s) may specify, or to provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review dispensing transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. (If the prescription drug outlet elects to comply with the latter requirement of providing equipment and/or personnel, the system must also be capable of printing the reports previously described.) Any failure or refusal by the pharmacist manager and/or a staff pharmacist to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these regulations.

h. It is the responsibility of the pharmacist manager to maintain records as required by Regulation 11.00.00.

7.00.30 Compliance of Outlet:

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

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 dispensed or active ingredients used in compounded preparations in the prescription drug outlet are procured 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.

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

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

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

**9.00.00 LEGAL PROCEEDINGS.**

9.00.10 Reporting.

a. The board shall be notified in writing within 72 hours of a 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. The licensee or registrant shall notify the Board in writing within 30 days of the disposition of such proceeding.

b. All Board licensees or registrants shall notify the Board in writing within 30 days of any disciplinary action in another state.

**10.00.00 EMERGENCY KITS.**

10.00.10 Application. Nursing homes, home health agencies, hospices, extended care facilities or intermediate care facilities licensed or certified by the Department of Public Health & Environment may maintain an emergency kit. Such kit is to provide an emergency supply of drugs, both controlled and non-controlled as provided below. The drugs maintained in the emergency drug supply shall remain the property of the pharmacy to whom the approval was issued. Emergency kits and the contents thereof shall meet the following requirements:

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

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

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

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

a. In the case of an approved facility (i.e. nursing homes, intermediate and extended care facilities, etc.) the medical director of the facility, or equivalent, and the consulting pharmacist shall determine the specific drugs to be kept in the kit. The number of drugs allowed in the kit shall be limited to sixty (60). Of the 60, twelve (12) may be controlled substances. The kit may contain no more than thirty (30) doses of any separate drug dosage form or strength for each drug. The container size for each drug shall be limited to unit dose or unit of issue packaging. Only an approved facility shall be permitted to have oral dosage forms of drugs in the kit.

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

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

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

10.00.40 Notification. A pharmacy which supplies an emergency drug kit to an approved facility or certified home health agency or licensed hospice shall notify the Board in writing within seven days that it has done so, specifying the name and address of the facility.

Notification must be repeated, within 30 days:

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

or

b. If there is a change of the consulting pharmacist, in the case of an approved facility, or of the designated pharmacist in the case of a certified home health agency or a licensed hospice.

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

10.00.51 The following information shall be placed on the outside of the kit and shall be readily visible and up-dated as required: name, address and telephone number of the prescription drug outlet providing the contents of the kit; the date of sealing; a suitable expiration date which shall be the earliest expiration date of any drug in the kit, but in no event shall it be more than one year from the date of sealing; and, in the case of an approved facility, the name of the consulting pharmacist, or, in the case of a certified home health agency or a licensed hospice, the name of the designated pharmacist. A copy of the kit contents shall also be attached to the outside of the kit.

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

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

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

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

10.00.70 Records. The prescription drug outlet providing the kit shall maintain a separate record of use for each drug placed in the kit, and for each kit provided, which shall state the name and address of the approved facility, certified home health agency, or licensed hospice; the name and strength of the drug; and the container size and the quantity initially placed in the kit. When a drug is removed for administration the prescription drug outlet shall obtain a prescription order for the drug within 72 hours after being notified that the kit was opened and the drug was used. The order shall indicate the total number of doses administered. The order shall be assigned a serial number and the order shall be retained as required by Regulation 11.04.10. Additionally, the

separate record required for each drug in the kit shall reflect the following information: date and quantity administered; names of both the patient and practitioner; date the drug was replaced in the kit; the quantity of the drug replaced, which shall not exceed the quantity administered or removed for administration; and the prescription order number assigned.

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

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

**11.00.00 RECORDS AND RECORDKEEPING.**

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. 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.

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 initials of the pharmacist 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 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.

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.

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 initials or other means of identification of the pharmacist 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;

(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.

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

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 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.

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. 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.

11.06.40 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.

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:

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.

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.**

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 has received notification by letter from the Board that, based on the evidence submitted, he or she is recognized by the Board as qualified to provide radiopharmaceutical services.

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

12.00.24 A "radiopharmaceutical" is any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any such drug which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

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

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

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

12.00.28 "Authorized practitioner" means a practitioner authorized by law to possess, use and administer

radiopharmaceuticals, acting within the scope of such authority.

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

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

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

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

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

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

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

12.00.42 Be a pharmacist licensed to practice in Colorado;

12.00.43 Submit to the Board either:

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

or

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

12.00.44 Upon application to the Board, in affidavit form, and upon the furnishing of such other

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

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

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

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

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

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

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

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

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

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

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

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

**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.

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.

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.

d. A consultant pharmacist shall visit the other outlet a minimum of one time each quarter to ensure compliance with the protocols and all applicable laws, rules, and regulations. The consultant pharmacist shall develop a form to document the visit and the results thereof. Such form shall be dated and signed by the consultant pharmacist and shall be maintained and available for inspection at the other outlet by the Board for a period of two years.

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

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

g. 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.

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 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).

**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 exmpt 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.

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.

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. aAny 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 wholesale outlet changes location, the outlet shall submit an application on a form provided by the Board prior to outlet relocation.

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, and 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 have 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 two 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 through the acquisition and sale by a wholesaler until final sale to a pharmacy or other person dispensing or administering the prescription drug. 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, 2010, 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.

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 distributor;

h. DEA number of distributor if a controlled substance; and

i. The DEA form 222 or an electronic order 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 the premises listed on the license. 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 two 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 are 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.

15.10.00 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 unsaleable prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation which shall be maintained for 3 2 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. A procedure to ensure that drugs are distributed only to individuals or entities with authorization to possess them.

i. A procedure to ensure that drugs are only distributed to the premises listed on the license or registration. 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.

j. A procedure to ensure verification of all transactions on a pedigree prior to distribution of the drug.

k. A procedure to ensure a pedigree is furnished when distribution occurs outside of the normal distribution channel.

l. 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.

16.00.30 Security. Limited access to controlled substances shall be maintained. Drugs shall be stored in locked cabinets or a safe bolted to the floor. Drugs shall be stored at the address registered with the Drug Enforcement Administration.

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

16.00.50 Records in General. All outlets registered and/or licensed by the Board shall maintain such records and inventories of prescription drugs as may be required by these 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.

16.00.60 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 limited licenses:

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

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

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

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

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

(a) All unexecuted DEA 222 forms.

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

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

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

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

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

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

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

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

(1) The name of the drug;

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

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

(4) All outdated controlled substances.

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

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

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

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

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

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

b. Animal weight, if available, or estimate.

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

d. Identification of individual administering drug.

e. Amount of drug wasted (if applicable).

f. Date administered.

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

16.01.00 Receipts.

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

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received if a controlled substance;

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

g. Name of the distributor;

h. 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.

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

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

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

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

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

16.02.01. Outlets are authorized to purchase, possess and administer drugs commonly used for the chemical capture of animals for control purposes or to sedate or immobilize pet animals prior to euthanasia. The drugs acceptable for this use are:

a. Acepromazine.

b. Ketamine.

c. Xylazine.

d. Tiletamine and Zolazepam.

e. Sodium Pentobarbital.

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

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

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

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

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

d. In the case of euthanasia training, the consultant or staff veterinarian must certify that staff has received thorough and adequate training on the proper administration of the medications

that comply with the dosage and routes guidelines of the American Veterinary Medical Association. Furthermore, the veterinarian must certify that he/she has provided direct supervision of staff administration of such drugs for at least 3 hours prior to staff administration without supervision.

**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 course of immunization delivery training endorsed by the centers for disease control and prevention (CDC). Proof of completion must be available at the pharmacist’s or pharmacy intern’s

main practice location.

(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 and certified in a program endorsed by the CDC with regard to CDC guidelines for both the administration of vaccines and treatment of severe adverse events following administration of a vaccine.

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.

**REGULATION NO. 11**

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|---|---|
| PART A: | General Provisions, Area of Applicability, Schedules for Obtaining Certification of Emissions Control, Definitions, Exemptions, and Clean Screen/Remote Sensing |
| PART B: | Standards and Procedures for the Approval, Operations, Gas Span Adjustment, Calibration and Certification of the Division Approved Test Analyzer Systems for Use in the Basic and Enhanced Program Areas, Test Analyzer Systems for Licensed Dealers in the Enhanced Area, and Clean Screen Test Analyzer Systems |
| PART C: | Inspection Procedures and Requirements for Exhaust Emissions, Fuel Evaporation Control, Visible Smoke Emissions, Emissions Control Systems, Chlorofluorocarbon Leak Detection, Clean Screening; and Practices to Ensure Proper Emissions Related Adjustments and Repairs |
| PART D: | Qualification and |

| | |
|---|---|
| | Licensing of Emissions Mechanics, Emissions Inspectors, and Clean Screen Inspectors; Licensing of Emissions Inspection and Readjustment Stations, Inspection-Only Stations, Inspection-Only Facilities, Fleets, Motor Vehicle Dealer Test Facilities and Enhanced Inspection Centers, Clean Screen Inspection Sites; and Registration of Emissions Related Repair Facilities and Technicians |
| PART E: | Prohibited Acts and Penalties to Ensure Proper Inspection Procedures, Adherence to Prescribed Procedures and Effective Emissions Related Repairs |
| PART F: | Maximum Allowable Emissions Limits for Motor Vehicle Exhaust, Evaporative and Visible Emissions for Light-Duty and Heavy-Duty Vehicles |
| PART G: | Statements of Basis, Specific Statutory Authority and Purpose |

**REFERENCES**

Pursuant to Section 24-4-103 (12.5), C.R.S., material incorporated by reference is available during normal working hours, or copies may be obtained at a reasonable cost, from the Technical Secretary of the Air Quality Control Commission c/o the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, Colorado 80246-1530 or material incorporated by reference within this regulation may be examined at any state publications depository library. References do not include later amendments to or additions of incorporated material

**Part A General Provisions, Area of Applicability, Schedules for Obtaining Certification of Emissions Control, Definitions, Exemptions, and Clean Screening/Remote Sensing**

**I. APPLICABILITY**

Subject to the provisions described in sections I.A and I.B of this Part A and pursuant to the schedule in section I.C of this Part A, all non-diesel fueled motor vehicles which are registered in the AIR Program area or which motor vehicle is owned or operated by a non-resident who meets the requirements of Section, 42-4-310(1)(c)(I), C.R.S., will be subject to an exhaust and evaporative emissions, chlorofluorocarbon, smoke opacity and emissions control, equipment inspection as a prerequisite to initial or renewal of the vehicle registration. Any person owning or operating a business and any post-secondary educational institution located in the program area as defined in subsection A of this section, excluding El Paso, Larimer, and Weld Counties, shall annually inform by written notice all persons employed by such business or attending classes that they are required to comply with the provisions of this regulation.

I.A. Geographic Areas of Applicability

This regulation shall apply to the AIR Program area as defined in Section 42-4-304(20), C.R.S.

I.B. Vehicles Eligible for AIR Program Inspection Procedures.

This regulation shall apply to all motor vehicles as defined in Section 42-4-304(18), C.R.S.

Beginning January 1, 2007, the AIR Program will no longer apply in El Paso, Larimer, and Weld County portions of the program area.

Vehicles that are registered in a program area and are being operated outside such area but within another program area shall comply with all program requirements of the area where such vehicles are being operated. Vehicles registered in a program area that are being temporarily operated outside the state at the time of registration or registration renewal may apply to the department of revenue for a temporary exemption from program requirements. Upon return to the program area, such vehicles must be in compliance with all requirements within fifteen days. A temporary exemption shall not be granted if the vehicle will be operated in an emissions testing area in another state unless proof of emissions from that area is submitted.

Pursuant to Section, 42-4-310(1)(c)(I), C.R.S. motorists operating vehicles in the enhanced program area shall comply with the provisions of the enhanced program.

The burden of proof in establishing an exemption from inclusion in all or any part of the AIR Program inspection requirements is on the vehicle owner.

I.C. Schedules for Obtaining Certifications of Emissions Control

I.C.1. REPEALED

I.C.2. Inspection schedules during calendar year 1995 and thereafter, vehicles are to be inspected according to the schedules established in Sections, 42-4-304(3)(b)(II), and, 42-4-310(1)(b)(II), C.R.S. as amended.

I.C.3. On or after October 1,1989, no used vehicle which is required to be registered in the program area shall be registered, unless such vehicle has a Certification of Emissions Control, or of Emissions Exemption. The seller of a used vehicle is required to obtain a Certification of Emissions Control for the new owner at the time of sale. This paragraph (3) does not apply to the sale of a motor vehicle which is inoperable or otherwise cannot be tested in accordance with this regulation if the seller of the motor vehicle provides a written notice to the purchaser pursuant to Section 42-4-310(4), C.R.S. If a motor vehicle is being registered for the first time in the program area, the owner shall obtain the certification and submit it with the application for registration to the Department of Revenue or an authorized agent of the Department of Revenue.

I.C.3.a. On or after October 1,1989, no used vehicle which is required to be registered in the program area shall be registered, unless such vehicle has a Certification of Emissions Control, or of Emissions Exemption. The seller of a used vehicle is required to obtain a Certification of Emissions Control for the new owner at the tune of sale. This paragraph (3) does not apply to the sale of a motor vehicle which is inoperable or otherwise cannot be tested in accordance with this regulation or that is being sold pursuant to part 18 (Vehicles Abandoned on Public Property) or part 21 (Vehicles Abandoned on Private Property) of article 4 of title 42, C.R.S. if the seller of the motor vehicle provides a written notice to the purchaser pursuant to Section 42-4-310(4), C.R.S. If a motor vehicle is being registered for the first time in the program area, the owner shall obtain the certification and submit it with the application for registration to the Department of Revenue or an authorized agent of the Department of Revenue.

I.C.3.b. An inspection is not required prior to the sale of a motor vehicle with at least twelve months remaining before the vehicle's certification of emissions compliance expires if such certification was issued when the vehicle was new. This subparagraph I.C.3.b. shall take effect upon the completion of necessary computer software changes or on January 1,2004, whichever comes first.

1.C.3.c. A motor vehicle being registered in the program area for the first time may be registered without an inspection or certification if the vehicle has not yet reached its fourth model year pursuant to 42-4-310(1)(a)(II)(C)C.R.S.

I.C.4. On or after October 1, 1989, and thereafter, any motor vehicle may be voluntarily inspected and a Certification of Emissions Control obtained which shall be valid as specified in section I.C.2. of this part A.

I.C.5. (Reserved)

I.C.5.a. As it pertains specifically to federally owned or leased vehicles, tactical military vehicles are not required to be inspected.

I.C.5.b. Federal installation managers are to declare all federal employee-owned vehicles operated on the installation and demonstrate that these vehicles have complied with periodic inspection requirements pursuant to 40 CFR Section 51.356(A)(4). Inspection results shall be reported to the Department of Revenue AIR Program section and up-dated based on inspection cycles.

I.C.6. (Reserved)

I.C.7. On or after January 1, 1995 fleets of twenty or more eligible vehicles shall be periodically inspected, comply with inspection provisions and obtain a Certification of Emissions Control.

I.C.7.a. Fleets may pursue licensing as a fleet inspection station under part D of this Regulation No. 11 pursuant to Section, 42-4-309, C.R.S. and comply with the provisions of that section.

I.C.7.b. Fleets may elect to comply with periodic inspection requirements under the provisions of Section 42-4-309 (2)(a), C.R.S. to include the inspection schedules of Sections 42-4-304(3)(b)(II) and 42-4-310(1)(b)(II)(a), C.R.S.

I.C.7.c. As it pertains to the fleet vehicles provisions pursuant to Section 42-4-309, C.R.S. and this subpart 7, municipal fleets of twenty vehicles or more may

comply with periodic inspection requirements as specified in Section 42-4-309(2)(a), C.R.S. to include inspection schedule of Sections 42-4-304(3)(b)(II) and 42-4-310 (1)(b)(II)(a), C.R.S.

I.C.8. New motor vehicles being registered with a Manufacturer's Statement of Origin (MSO), Manufacturer's Certificate of Origin (MCO) or similar document shall be issued a registration without a Certificate of Emissions Control.

Such new motor vehicles are to be issued a Verification of Emissions Test exemption windshield sticker at the time of sale and valid for up to four (4) years. The selling dealer is responsible for obtaining the Verification of Emissions Test.

New vehicles under this section shall also include those new vehicles leased under an MSO or MCO or similar document and four years without an inspection. After the fourth year or a transfer of ownership, such vehicles shall be issued a registration only with a Certificate of Emissions Control. The inspection schedule for these vehicles shall then revert to a biennial cycle.

I.C.9.a. Compliance with AIR Program inspection requirements will not be required for wholesale transactions between motor vehicle dealers licensed pursuant to Article 6 of Title 12, C.R.S.

I.C.9.b. Effective January 1, 2004, or upon the completion of necessary computer software changes, whichever comes first, motor vehicle dealers shall have motor vehicles inventoried or consigned for retail sale inspected annually. A further inspection is not required at the time of sale if:

i. For a 1982 or later motor vehicle, there are at least twelve months remaining before the vehicle's certification of emission compliance expires and the dealer has had the vehicle inspected since acquiring it. Such a vehicle purchased from a licensed motor vehicle dealer may be registered in the program area without an inspection if, on the date of vehicle registration, at least twelve months remain before the expiration of such certification.

ii. For a 1981 or earler motor vehicle, the vehicle has a valid certification of emission compliance and the dealer has had the vehicle inspected since acquiring it. Such a vehicle purchased from a licensed motor vehicle dealer may be registered in the program area without an inspection if, on the date of vehicle registration, at least nine months remain before the expiration of such certification.

I.C.10. For purposes of Sections 42-4-304(3), 42-4-309(3) and 42-4-310, C.R.S., a certificate of emissions Control shall be considered to be issued at the time of sale or transfer of a vehicle if such certificate is issued pursuant to an inspection conducted no later than the date of such sale or transfer, and no earlier than one hundred twenty calendar days prior to such sale or transfer.

I.C.11. Eligible fleets as defined in Section 42-4-309, C.R.S. that declare not to self-inspect shall be inspected according to the same schedules, subject to the same emissions related repair requirements and waiver provisions as non-fleet vehicles.

I.C.12. For the purposes of 42-4-309(6)(B) if a vehicle fails the test or is untestable due to mechanical and/or electrical/electronic problem, the motorist shall have the same recourse as that of not passing an inspection. However, Section 42-4-309(6), C.R.S. and the regulations implementing such provision, shall not be federally enforceable, and shall

not be incorporated into the State Implementation Plan.

## II. DEFINITIONS

1. "Accreditation" means certification that the instrument and instrument manufacturer meet the operating criteria specifications and requirements of the Colorado Department of Health, Air Quality Control Commissions as specified in Part B of this regulation.

2. "Air Intake Systems" are those systems which allow for the induction of ambient air (to include preheated air) into the engine combustion chamber for the purpose of mixing with a fuel for combustion.

3. "AIR Program Station" is an Automobile Inspection and Readjustment (AIR) Station that qualifies and is licensed to operate as an emissions inspection and readjustment station.

4. "Air System" is a system for providing supplementary air into the vehicle's exhaust system to promote further oxidation of HC and CO gases and to assist catalytic reaction.

5. "BAR 90" refers to the California Bureau of Automotive Repair specifications for Exhaust Gas Test Analyzer Systems (TAS) which became effective in 1990.

6. "Basic Engine Systems" are those parts or assemblies which provide for the efficient conversion of a compressed air/fuel charge into useful power to include but not limited to valve train mechanisms, cylinder head to block integrity, piston-ring-cylinder sealing integrity and post-combustion emissions control devise integrity.

7. "Calibration" is the process of establishing or verifying the total response curve of an exhaust gas analyzer. Calibration is a laboratory procedure using several different calibration gases having precisely known concentrations.

8. "Calibration Gases" are gases of precisely known concentration which are usually used in the laboratory as references for establishing or verifying the calibration curve of an exhaust gas analyzer.

9. "Catalytic Converter" is a post-combustion device which oxidizes HC and CO gases and/or reduces oxides of nitrogen.

10. "Certification" means assurance by the authorized source, whether it be a laboratory, the manufacturer, or the State, that a specific product or statement is in fact true and meets all required accreditation requirements.

11. "Chlorofluorocarbon" (CFC) is a class I stratospheric ozone depleting compound as listed in appendix A, final rule vol.57.mp 147 Federal Register, 40 CFR part 82.

12. "Clean Screen Inspection Site" is that location within the program area as defined in Section 42-4-304(20)(a), C.R.S., approved by the Division and the Department of Revenue.

13. "Clean Screen Inspector" is a person found qualified by the Division, and licensed by the Executive Director to operate Clean Screen Inspection equipment.

14. "Clean Screen Program" is that program as defined in Section 42-4-304(3.5), C.R.S.

15. "Clean Screened Vehicle" is a vehicle which is eligible for inspection, has at least two consecutive passing emissions readings performed on different days or at different approved Clean Screen Inspection Sites prior to its registration renewal date, and has otherwise complied with the

provisions of Section IV of this Part A, and Section VI of Part F.

16. “Clean Screen Data Manager” is that person or entity that contracts with the state to provide clean screen data management functions. This same person or entity may also act as general contractor in conducting and facilitating clean screen inspections.

17. “Colorado '94” refers to those test analyzer systems which are based on BAR '90 but modified as specified by the Division for use in the AIR Program for the period of time after January 1,1994 through December 31,2001.

18. Colorado Automobile Dealer Transient Mode Test Analyzer System is a dynamometer based inspection system capable of performing an inspection grade (I/G 240) emissions inspection procedure under simulated driving conditions. The procedure is intended for determining the compliance status for used vehicles prior to retail sale.

19. “Compliance” means verification that certain submission data and hardware submitted by a manufacturer for accreditation consideration, meet all required accreditation requirements.

20. “Division” is the Air Pollution Control Division of the Colorado Department of Public Health and Environment.

21. “Electrical, Electronic, or Electro-mechanical Span” is the adjustment of an exhaust gas analyzer using an electronic signal rather than a calibration or span gas as a reference source.

22. “Emissions Control Systems” are those parts, assemblies or systems originally installed by the manufacturer in or on a vehicle for the purpose of reducing emissions.

23. “Executive Director of the Department of Revenue” or “Executive Director” is the representative of the Department of Revenue or designee responsible for the field enforcement of the AIR Program, licensing of emissions mechanics, clean screen inspectors and inspection stations.

24. “Fuel Control Systems” are those mechanical, electro-mechanical, galvanic or electronic parts or assemblies which regulate the air/fuel ratio in an engine for the purpose of providing a combustible charge.

25. “Fuel Filler Neck Restrictor system” is the orifice and obstruction (“Flapper Door” ) in the gas tank filler neck that prevents the insertion of a “leaded gasoline” nozzle and deters the introduction of “leaded fuel” .

26. “Gas Span” is the adjustment of an exhaust gas analyzer to correspond with known concentrations of span gases.

27. “Gas Span Check” is a procedure using known concentrations of span gases to verify the gas span adjustment of an analyzer.

28. “Gross Vehicle Weight (GVW) Rating” is the maximum recommended combined weight of the motor vehicle and its load as prescribed by the manufacturer and expressed on a permanent identification label affixed to the motor vehicle.

29. “Heavy Duty Vehicles (HDV)” are those motor vehicles for model years 1978 and earlier having a GVW rating of greater than 6000 pounds and for model years 1979 and newer, having a GVW rating of greater than 8,500 pounds.

30. “Idle Mode” means a condition where the vehicle engine is warm and running at the rate specified by the manufacturer's curb idle, where the engine is not propelling the vehicle, and where the throttle

is in the closed or idle stop position.

31. “Ignition Systems” are those parts or assemblies which are designed to cause and time the ignition of a compressed air/fuel charge.

32. “Inspection Area” is the area that is occupied by the analyzer, sample hose and the vehicle being inspected.

33. “Inspection-only station” is that licensed station within the basic program area as defined in Section 42-4-304(2), C.R.S., which meets the requirements of Section 42-4-308, C.R.S., which facility the operator is licensed to operate by the Executive Director as an inspection-only station.

34. “Instrument” is the complete system which samples and reads out the concentration of pollutant HC and CO gas plus CO2 gas. The instrument includes the sample handling system, the exhaust gas analyzer and the enclosure cabinet.

35. “Light Duty Vehicles (LDV)” are those motor vehicles (to include trucks) for model years 1978 and earlier having a GVW rating of 6,000 pounds or less and for model years 1979 and newer having a GVW rating of 8,500 pounds or less.

36. “Motor Vehicle Emissions Compliance Inspectors (ECI)” are those persons employed and authorized by the Department of Revenue for licensing and enforcement of the AIR Program.

37. “Original Condition” means the condition as installed by the manufacturer but not necessarily to the original level of effectiveness.

38. “Program Area” is that geographic area defined in Section 42-4-304(20), C.R.S.

39. “Registration Renewal Date” is the last day of the month in which the vehicle registration expires as defined in Section 42-3-103, C.R.S.

40. “Span Gases” are gases of known concentration used as references to adjust or verify the adjustment of an exhaust gas analyzer's span settings.

41. “State Emissions Technical Center Personnel” are those persons employed by or authorized by the Department of Health for technical or administrative support of the AIR Program.

42. “Test Analyzer Systems” (TAS) in the context of this regulation is that analytical instrumentation used to measure automotive emissions and prompt the operator through other elements of an emissions inspection.

43. “True Concentration” is the concentration of the gases of interest as measured by a standardized instrument which has been calibrated with 1% precision gases traceable to the National Institute for Standards and Technology.

44. “Zero Gas” is a gas, usually air or nitrogen, which is used as a reference for establishing or verifying the zero point of an exhaust gas analyzer.

**III. EXEMPTION FROM SECTION 42-4-314, C.R.S. FOR DEPARTMENT OF DEFENSE PERSONNEL PARTICIPATING IN THE PRIVATELY OWNED VEHICLE IMPORT CONTROL PROGRAM.**

III.A. U.S. Department of Defense (DOD) personnel participating in the DOD POV (privately owned vehicle) Import Control Program operating a 1975 or subsequent model year automobile, are exempt from the prohibition of C.R.S., 42-4-314(2), C.R.S. insofar as it pertains to filler neck restrictors, catalytic converter systems, and, if applicable, exhaust gas oxygen (O2) sensor(s), if

one of the following conditions are met:

III.A.1. The automobile will be driven to the port and surrendered for exportation under said program within ten (10) working days of disconnection, deactivation, or inoperability of the restrictor, catalytic converter systems, or exhaust gas oxygen (O2) sensor(s); or

III.A.2. The reconnection, reactivation, or reoperability of the restrictor, catalytic converter systems, and, if applicable, exhaust gas oxygen (O2) sensor(s), is made within ten (10) working days from the time the owner picked up the automobile at the port.

III.B. Persons disconnecting, deactivating, or rendering inoperable any filler neck restrictor, catalytic converter system, exhaust gas oxygen (O2) sensor(s) on 1975 or subsequent model year automobile of DOD personnel participating in the DOD POV Import Control Program which will be driven to the port and surrendered for exportation under said program within ten (10) working days are exempt from the prohibition of 42-4-314, C.R.S.

III.C. Unless otherwise exempt under this section III of part A, vehicles shall be required to be configured as a vehicle certified by the EPA for sale and use within the United States pursuant to 40 CFR, Part 86, Subpart A.

**IV. CLEAN SCREEN/REMOTE EMISSIONS SENSING**

IV.A. Geographic Area of Applicability

IV.A.1. The Clean Screen Program shall initiate as established in Section 42-4-306(23), C.R.S., in the Larimer and Weld County elements of the basic program area as defined in Section 42-4-304(2), C.R.S. Effective January 1, 2007 this subpart IV.A.1. of Part A is repealed.

IV.A.2. The Clean Screen Program as established in section 42-4-306(23) C.R.S., shall include the enhanced program area.

IV.A.3. The El Paso county portion of the basic emissions program area shall be excluded from the clean screen program.

IV.B. Vehicles Eligible to participate in the Clean Screen/Remote Emissions Sensing Program

IV.B.1. The clean screen program established in this subpart IV of Part A shall apply to eligible motor vehicles as defined in 42-4-310(5)(a), C.R.S., for which registration will expire within twelve months, a certificate of emissions control is a prerequisite to renewal and which are registered in a clean screen program county.

IV.B.2. The counties of Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, Jefferson, Larimer, and Weld are clean screen counties. Effective January 1, 2007 this subpart IV.B.2.of Part A is repealed.

IV.B.3. Effective January 1, 2007, the counties of Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson are clean screen counties.

IV.C. REPEALED

IV.D. Enhanced program area phase-in schedule

Based upon the schedule specified below, remote emissions sensing procedures shall be introduced in the enhanced program area as defined in Section 42-4-304(20)(c)(I) and (II) only to

the extent such phase-in schedule is consistent with, and made possible by, the schedule promulgated by the Commission pursuant to Section 42-4-134(26.5)(a), C.R.S.

IV.D.1. For purposes of the clean-screen program, no more than twenty percent of the fleet of gasoline vehicles in the enhanced program area will be evaluated with remote sensing between March 1, 2002 and February 28, 2003.

IV.D.2. For purposes of the clean-screen program, no more than forty percent of the fleet of gasoline vehicles in the enhanced program area will be evaluated with remote sensing between March 1, 2003 and February 29, 2004.

IV.D.3 For purposes of the clean-screen program, no more than sixty percent of the fleet of gasoline vehicles in the enhanced program area will be evaluated with remote sensing during any twelve month period between March 1, 2004 and December 31, 2005.

IV.D.4 For purposes of the clean-screen program, no more than fifty percent of the fleet of gasoline vehicles in the enhanced program area will be evaluated with remote sensing during any twelve-month period after December 31, 2005.

IV.E. Schedule for collection of emissions inspection fees by county clerks and recorders.

IV.E.1. Beginning with motor vehicles with registration renewals coming due in November 2002, the clerks and recorders for the counties of Larimer and Weld shall collect an emissions inspection fee in the amount specified pursuant to Section 42-3-134(26.5)(a)(I), C.R.S., at the time of registration of a motor vehicle that the Department of Revenue has determined to have been clean screened, unless a valid certification of emissions compliance has already been issued for the vehicle being registered indicating that the vehicle passed the applicable emissions test at an enhanced inspection center, inspection and readjustment station, motor vehicle dealer test facility, or fleet inspection station.

This section IV.E.1. shall not apply until the Colorado Department of Revenue and the Air Pollution Control Division determine that all requisite computer programming changes necessary for the functioning of the pay-upon-registration system have been completed, and that the pay-upon-registration system will function properly in such counties.

Effective January 1, 2007 this subpart IV.E.1 of Part A is repealed.

IV.E.2. Beginning with motor vehicle registration renewals coming due in April 2003, the clerks and recorders for the counties of Adams, Arapahoe, Boulder, Broomfield, Denver, Douglas, and Jefferson shall collect an emissions inspection fee in the amount specified pursuant to Section 42-3-134(26.5)(a)(I), C.R.S. at the time of registration of a motor vehicle that the Department of Revenue has determined to have been clean screened, unless a valid certification of emissions compliance has already been issued for the vehicle being registered indicating that the vehicle passed the applicable emissions test at an enhanced inspection center, motor vehicle dealer test facility or fleet inspection station.

This Section IV.E.2. shall not apply until the Colorado Department of Revenue and the Air Pollution Control Division determine that:

I. All requisite computer programming changes necessary for the functioning of the pay-upon-registration system have been completed;

II. The test equipment is in place and its reliability has been verified; and

III. A test run demonstrates that the system will accurately send notices to the correct vehicles.

IV.F. Repeal

This section IV shall be repealed effective December 31, 2007.

**Part B Standards and Procedures for the Approval, Operation, Gas Span Adjustment, Calibration and Certification of the Division Approved Test Analyzer Systems for Use in the Basic and Enhanced Areas and Test Analyzer Systems for Licensed Dealers in the Enhanced Area**

**I. APPROVAL OF THE COLO '94 TEST ANALYZER SYSTEMS**

I.A. From January 1, 1995 and thereafter no emissions inspection required by the AIR Program in the basic program area or inspection-only facilities in the enhanced program area shall be performed unless the instrument used for measuring exhaust gases from motor vehicles is identified as a Colorado AIR Program COLO '94 exhaust gas analyzer. Sources of vendors for the approved analyzers may be obtained from the Program Administrator, Mobile Sources Section, Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver CO 80246-1530.

I.B. As an element of accreditation, the Division will accept a Certification statement for the exhaust gas analytical and sampling system portion of the Colorado AIR. Program COLO'94 exhaust gas analyzer from the California Bureau of Automotive Repair (BAR) or a recognized laboratory. The manufacturers' compliance with the revisions and additions to the specifications necessary for use of the instrument within the AIR Program will be determined by the Division or its designee. Those testing procedures are to be included with the bid specifications.

I.C. The following statement is a requirement of the AIR Program for approval of an exhaust gas analyzer and is included to make manufacturers and purchasers of exhaust gas analyzers aware of the warranty requirements of Section 207(b) of the federal Clean Air Act, as amended 1981.

207(b) Warranty Requirements:

Unless an exhaust gas analyzer has been certified by the manufacturer as having met the specifications of 40 CFR Part 85, Subpart W as published in Part IX of the May 22, 1980 Federal Register, an inspection performed using that analyzer may not qualify a 1982 or later model year vehicle for warranty repair coverage according to the provisions of the Emission Control System Performance Warranty (Section 207(b) of the federal Clean Air Act).

**II. APPLICATIONS FOR APPROVAL OF COLO'94 TEST ANALYZER SYSTEMS EQUIPMENT MANUFACTURERS**

Those manufacturers wishing to participate in the open bid process shall make application with the Air Pollution Control Division, Mobile Sources Section, of the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver, CO 80246-1530 on forms provided thereby. All manufacturers making application shall meet the requirements as specified by the Department of Administration and the Procurement Code, Articles 101-112 of Title 24, C.R.S.

A manufacturer requesting the approval of an instrument for the measurement of exhaust gases for use in the AIR Program station shall make application therefor with the Air Pollution Control Division, 4300 Cherry Creek Drive South, Denver, CO 80246-1530 on forms provided thereby. All manufacturers making application shall meet the technical specifications and administrative requirements specified by the Air Pollution Control Division.

## III. PERFORMANCE AND DESIGN SPECIFICATIONS FOR THE COLO'94 EXHAUST GAS ANALYZERS

Pursuant to Section 42-4-306(3)(a), C.R.S the specifications for the exhaust gas analyzer required for inspections conducted July 1,1987 and thereafter are attached to this regulation as appendix A. These specifications include but are not limited to the provisions of California BAR'90, data collection, service/maintenance, requirements for replacement or loan instruments and warranty for the period of the agreement. These specifications are described in a separate document entitled “Colorado Department of Public Health and Environment Specifications for Colorado '94 Analyzer - Hardware Specifications” March 17, 1994 as adopted by the Commission. This information is available from the Air Pollution Control Division, Mobile Sources Section, 4300 Cherry Creek Drive South, Denver, CO 80246-1530. Those manufacturers making application should refer to section II of this Part B.

The Division in its discretion may accept substitute specifications for Test Analyzer Systems provisions that such substitute specifications are equivalent to those contained in Appendix A.

## IV. SPAN GASES FOR USE WITH COLO'94 TEST ANALYZER SYSTEMS

IV.A. General

The instrument manufacturer and his designated marketing vendors shall, supply span gases approved by the Division to any ultimate purchaser of his unit. The instrument manufacturer shall also provide the analyzer purchaser with a comprehensive, up-to-date list (with addresses and phone numbers) of gas blenders approved by the Division. Each new or used instrument sold by the instrument manufacturer or marketing vendor shall have full span gas containers installed and operational at time of delivery.

IV.B. Span Gas Blends

The span gas concentrations supplied to the AIR Program stations shall conform to the specifications contained in section VI. of this Part B.

Only gas blends supplied by Division approved blenders selected pursuant to Section 42-4-306(3)(a)(I)(C) shall be offered for sale in Colorado.

Pursuant to Section 42-4-306(3)(a)(I)(C), the Division shall select blenders authorized to provide span gases that comply with the standards and specifications set out in Appendix B. The requirement to use gases procured pursuant to the standards and specification in Appendix B shall not be federally enforceable, and shall not be part of the State Implementation Plan.

IV.C. Optical Correction Factor [also referred to as “C” factor, propane to hexane conversion factor” (P.E.F.)].

Each instrument shall be permanently labeled with its correction factor visible from the outside of its cabinet. The correction factor shall be carried to at least two decimal places eg., (0.52). Factor confirmation shall be made on each assembled analyzer by measuring both N-hexane and propane on assembly line quality checks. P.E.F. limitations are described in the specifications document attached to this regulation as Appendix A.

IV.D. Running Changes and Equipment Updates

Any changes to design or performance characteristics of component specifications which may affect instrument performance must be approved by the Commission. It will be the instrument manufacturer's responsibility to confirm that such changes have no detrimental effect on analyzer performance. All Colorado COLO'94 exhaust gas analyzers will be updated as needed and as

specified in the specifications document.

## V. DOCUMENTATION, LOGISTICS, AND WARRANTY REQUIREMENTS

V.A. Instruction Manual

The instruction manual accompanying each analyzer shall contain at least the following:

V.A.1. Complete technical description.

V.A.2. If available, functional schematics (mechanical and electrical).

V.A.3. Accessories and options (included and/or available).

V.A.4. Model number, identification markings and location.

V.A.5. Operating maintenance to include periodic recommendations, i.e., daily, weekly, monthly, and procedure for maintaining sample system integrity (leaks, hangup, calibration, filters, etc.).

V.A.6. Required service schedule identifying the items needing maintenance and the procedures to be followed by the purchaser. The services to be performed only by the manufacturer shall be clearly identified.

V.A.7. Warranty provisions to include listing of warranty repair stations by name, address, and phone number.

V.A.8. The name, address, and phone number of the permanent Colorado representative offering training, service, warranties, etc.

V.A.9. Information and terms of manufacturers service contract clearly stating the coverage including but not limited to each party's obligation, period of coverage, cost, service response times, availability of loaner units. Manufacturer or designee performed service/maintenance provisions and costs shall be so stated for the duration of the program and annually up-dateable costs.

## VI. CALIBRATION OF COLO'94 TEST ANALYZER SYSTEMS

The Division shall use and require for use in the calibration and spanning of exhaust gas analyzers span gases and containers supplied by authorized blenders meeting the following parameters, blends, and specifications:

VI.A. Standardizing Instruments

The calibration gases for standardizing instruments shall conform to the provisions outlined in 40 CFR, Section 86.114 (July 1, 1992) (EPA) for automotive exhaust emissions testing. Those gases shall be of “precision” quality, certified to be within ±1% of the labeled concentration, and traceable to the National Institute for Standards and Technology (NIST).

VI.B. AIR Program Station Instruments

The span gases supplied to AIR Program stations shall conform to the following:

VI.B.1. Tri-blends of HC, CO, CO2 in a carrier gas of nitrogen (N2). The hydrocarbon (HC) gas will be propane.

VI.B.2. The concentrations) of the span gas blends (two) shall be within limits established by the Division to provide for uniform exhaust gas analyzer spanning. The Division may establish such limits to ensure gasses are measurable based upon the ranges or scales of the equipment.

VI.B.3. The accuracy of the AIR Program station span gas blend shall be certified by the blender to be ±2% of labeled concentration and traceable to the NIST.

VI.C. AIR Program stations will gas calibrate the exhaust gas instrument once every 72 hours as determined by the instrument or as needed in order to maintain accuracy.

VI.D. All AIR Program exhaust gas analyzers will be calibrated only with span gases bearing a Colorado approval label.

VI.E. Additional specifications related to calibration requirements are described in the specifications document attached to this document as Appendix A.

## VII. APPROVAL OF THE COLORADO AUTOMOBILE DEALERS TRANSIENT MODE TEST ANALYZER SYSTEM

Any applicable emissions inspection required by the AIR Program performed by a licensed Motor Vehicle Dealers Test Facility pursuant to Section 42-4-304 (19), C.R.S., in the enhanced program area, shall be performed utilizing a Colorado Automobile Dealer Transient Mode (I/G 240) test analyzer system approved by the state open bid process. Sources of vendors for the approved test system may be obtained from the Program Administrator, Mobile Sources Section, Air Pollution Control Division, Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver Colorado 80246-1530.

This section VII, and the associated design and performance specifications set out in Appendix A, attachment III, shall not be federally enforceable and shall not be part of the State Implementation Plan.

## VIII. APPLICATIONS FOR APPROVAL OF THE COLORADO AUTOMOBILE DEALERS TRANSIENT MODE TEST ANALYZER SYSTEM

Those manufacturers wishing to participate in the open bid process shall make application with the Air Pollution Control Division, Mobile Sources Section, of the Colorado Department of Public Health and Environment, 4300 Cherry Creek Drive South, Denver Colorado 80246-1530 on forms provided thereby. All manufactures making application shall meet the requirements as specified by the Department of Administration and Procurement Code, Articles 101-112 of Title 24, C.R.S.

The design and performance specifications for the Colorado Automobile Dealers Transient Mode Test Analyzer System Technical and Hardware Specification Document of January 27. 1997 attached as Appendix A, attachment III. Pursuant to 42-4-306 (3)(a)(I)(C), the Division shall let bids for the procurement of instruments that comply with such specifications. In addition to the specifications set out in Appendix A, attachment III, qualifying bids shall:

Include a bid for the procurement of any working/support and span gases necessary for the operation of such Colorado Automobile Dealers Transient Mode Test Analyzer System, unless all such gases are already subject to a contract issued pursuant to 42-4-306 (3) (a) (I) (C). Any bid for the procurement of such gases shall comply with the relevant requirements of Part B, IV of the Regulation 11 and relevant requirements of Standards and Specifications for Calibration and Span Gas Suppliers, attached as Appendix B, including the “Gas Requirements for the Basic and Enhanced Inspection Test Programs, 1997” as set out in section 5 of Appendix B.

Include a comprehensive and up-to-date list of working/support and span gas suppliers subject to a

contract issued pursuant to 42-4-306(3) (a) (I) (C). A copy of such list shall be provided to each purchaser.

Provide for the Division-approved calibration gases for calibration of the Colorado Automobile Dealers Transient Mode Test Analyzer System.

A service and maintenance plan, including a description of services, service response times, periodic maintenance schedules and annual service agreement costs inclusive of all services necessary to comply with the Colorado Automobile Dealers Transient Mode Test Analyzer System Technical and Hardware Specification Document of January 27, 1997. Service agreement costs are to be listed annually and shall be for the remaining period of the AIR Program.

**IX. REQUESTS FOR APPROVAL OF CLEAN SCREEN TEST ANALYZER SYSTEMS**

IX.A. REPEALED

IX.B. Calibration gas blends intended for Clean Screen Test Analyzer Systems shall be verified and approved subject to the requirements of Standards and Specifications for Calibration and Span Gas Suppliers including Gas Requirements for the Basic and Enhanced Inspection Test Programs. 1997, (Appendix B).

Concentrations of calibration gases noted above are to be determined pending system configuration, operating ranges and expected emissions readings.

State audit blends for Clean Screen Test Analyzer Systems shall be of varying concentrations of and shall conform to the above gas blending standards.

**Part C Inspection Procedures and Requirements for Exhaust Emissions, Fuel Evaporation Control, Visible Smoke Emissions, Emissions Control Systems, Chlorofluorocarbon Leak Detection; and Practices to Ensure Proper Emissions Related Adjustments and Repairs**

**I. PRE-INSPECTION REQUIREMENTS**

I.A. All aspects of the inspection must be performed by a licensed emissions mechanic, licensed emissions inspector or authorized emissions inspector. It is the responsibility of emissions mechanics and emissions inspectors to notify the Department of Revenue of their current place of employment and any subsequent transfer, and place of residence. The Contractor shall be responsible for its personnel and notifying the Department of all personnel assignments and adjustments in those assignments.

The emissions mechanic not employed by an “Inspection-Only Station” shall notify the customer prior to initiating an emissions inspection if he/she is unable to perform the required adjustments and/or repairs for that particular vehicle should that vehicle fail the inspection. Otherwise the emissions mechanic shall not conduct an inspection on a motor vehicle unless that emissions mechanic so notifies the customer or is able to perform the adjustment and/or repair procedures for that particular vehicle as prescribed by the manufacturer and specified by subpart IV of this part.

I.B. Inspections may only be performed on the premises of the licensed address as prescribed in Part D section (I)(A)(2). The entire inspection shall take place within the reach of the analyzer hose.

I.C. In consideration of maintaining inspection integrity:

I.C.1. The temperature of the inspection area when utilizing one or more test analyzer systems as specified in Part B of this regulation shall be between 41°F and 110°F (50°C and 43°C) during the inspection. Inspection area temperatures must be accurately recorded,

and monitored in a well-ventilated location away from vehicle engine and exhaust heat sources and out of direct sunlight. The inspection area includes the vehicle being inspected.

I.C.2. The test analyzer system and other inspection equipment shall be kept in an area within the facility which affords adequate protection from the weather.

I.C.3. A permanent location which meets all applicable requirements of this rule to provide for the inspection of vehicles is required. Electrical supply must be public utility designated for that area and meeting the analyzer manufacturer's requirements for to the test analyzer system is to be dedicated to this purpose. A dedicated phone service with dial-up back-up is required to facilitate operation of the data-communications system.

I.D. Upon a physical verification of the vehicle identification number (VIN) and license plate number, the emissions mechanic or emissions inspector will enter this information into the program database in order to match this information with the state registration record. In the case of a match, the emissions mechanic or emissions inspector shall proceed. If no match is found, a new inspection record will be created. All non-Colorado registered vehicles and first time registrations with the State of Colorado will require the creation of a new inspection record by the emissions mechanic or emissions inspector.

I.E. The emissions mechanic or emissions inspector shall ascertain from the inspection record data base if an initial inspection or an after-repairs inspection is to be conducted. If an after-repairs inspection is to be conducted, previous inspection data is required for comparison. Specific emissions related repair information as specified in section VII (B) of this Part C shall be entered to the data base. Inspections conducted within 60 days of the initial inspection date are to be considered an after-repairs inspection. Inspections conducted greater than 60 days from the initial inspection date are to be considered initial inspections. The emissions mechanic or emissions inspector shall accurately enter vehicle, and last inspection information as required for vehicle emissions inspection records.

I.F. The emissions mechanic or emissions inspector shall perform a cursory safety assessment of the motor vehicle prior to inspection. If in the opinion of the emissions mechanic or emissions inspector the vehicle is unsafe to inspect due to engine/drive-line metallic noises, or leaking fluids, the request for inspection may be refused.

**II. EXHAUST EMISSIONS INSPECTION PROCEDURES**

II.A. All model year vehicles to be inspected at licensed emissions inspection stations within the basic program area and at inspection-only facilities in the enhanced program area shall be administered an EPA approved idle short test as specified in 40 CER, Part 51, Subpart S, Appendix B.

The emissions mechanic or emissions inspector will use a certified TAS to select the appropriate idle short test cycle based upon the make, model year engine family and vehicle classification. These idle short tests include, but may not be limited to, a standard single speed idle test; the pre-idle 30-second pre-conditioning idle test with the high speed (2500 ± 300 RPM) pre-conditioning cycle before the idle mode; a standard two speed (3 - mode) idle test with the raised idle segment at 2500 ± 300 RPM; second chance raised idle pre-conditioning for 30 seconds just prior to the idle mode after an initial failure, and second chance restart in which the ignition is turned off for ten (10) seconds and then restarted to complete the emissions inspection procedure. All sampling modes shall (each) be thirty seconds in duration and raised engine speed modes be it for pre-conditioning or sampling, shall be 2500 RPM ± 300 RPM. As a pass/fail determination, the vehicle's emissions levels must be the same as or less than applicable limits at the designated engine speed(s) in order to pass.

II.B. The entire vehicle shall be in normal operating condition and at normal operating temperature, which shall be determined by carefully feeling the top radiator hose while the engine is not operating, by checking the temperature gauge, and/or operating the vehicle prior to performing the idle emissions inspection. Vehicles are not to be idled for extended periods of time but rather inspected in an expedious manner as soon as normal operating temperature is achieved. The vehicle shall be inspected in an as-received condition.

The inspection shall be performed with the transmission in park or neutral and with all accessories off.

II.B.1. The analyzer probe shall be inserted at least twelve (12) inches or as recommended by the analyzer manufacturer for a quality sample whichever is greater.

II.B.2. For all vehicles equipped with a multiple exhaust system, the analyzer's dual exhaust procedure must be used.

II.B.3. If a baffle or screen prevents probe insertion to an adequate depth, a suitable probe adapter or snug fitting hose which effectively lengthens the exhaust pipe may be used.

II.B.4. The appropriate emissions limits specified in Part F of this regulation will be utilized by the certified test analyzer system. In selecting appropriate emissions limits, for motor vehicles of model years 1978 and earlier having a gross vehicle weight (GVW) rating of greater than 6000 lbs., or of model years 1979 and newer having a gross vehicle weight rating of greater than 8500 lbs.: the emissions mechanic or emissions inspector shall identify that particular vehicle's GVW rating by examining the vehicle information (metal) plate or sticker. These motor vehicles will be subject to the applicable emissions limits as listed in Part F of this regulation. If the vehicle information plate or sticker is missing, illegible or the GVW rating information is not otherwise available, the emissions mechanic or emissions inspector shall examine the engine exhaust emissions control information label which is permanently affixed to the engine and determine heavy-duty engine/vehicle federal certification status. Vehicle engines not labeled as having complied with applicable U.S. EPA heavy-duty regulations by the manufacturer are assumed to be light-duty vehicles and subject to the emissions limits listed in Part F of this regulation. Emissions limits for vehicles in which the engine has been changed shall be based upon whichever is newest, the vehicle or the replacement engine, as specified on a vehicle evaluation form (DR2365) or bar coded label generated by emissions technical center staff or designee.

II.C. In the event the tachometer over-ride mode must be utilized to inspect a vehicle, an accurate auxiliary tachometer must be used to verify engine speeds mandated in subpart A of this section.

II.D. The vehicle will be evaluated for the presence of visible smoke emissions. The evaluation is to be performed during all (engine) operating conditions of the inspection procedures prescribed in subparts A through G of this section II.

II.E. A Certification of Emissions Compliance shall be issued if the vehicle passes the emissions control systems inspection (for 1975 and newer model year vehicles only), the exhaust and evaporative emissions inspection, and there is no evidence of visible smoke emissions.

II.F. If the vehicle fails the initial emissions inspection the owner is to have appropriate emissions related repairs or adjustments made and may return the vehicle to an AIR Program station, facility or center, as appropriate, for reinspection. Within ten (10) calendar days of the initial test, one free reinspection shall be provided to the motorist if the vehicle is returned to the same station or facility at which the initial test was performed. A motorist shall be entitled to one free after-repairs test at any contractor operated center within ten (10) calendar days of the initial test performed at

a contractor operated center. If during repairs, it is determined the necessary parts are not available, the motorist may be issued a temporary Certificate of Emissions Control by Department of Revenue personnel. Proof of part(s) non-availability as described in subpart III.E. of this part is required. Motorists pursuing a temporary Certificate of Emissions Control must facilitate final vehicle inspection and compliance with adopted regulation.

II.G. Model year 1982 and newer light-duty vehicles to be inspected at licensed enhanced inspection centers within the enhanced program area shall be administered an EPA approved transient loaded mode inspection procedure as specified in 40 CFR, Part 51 Subpart S Federal Register Volume 57, Number 215, November 5,1992.

II.G.1. Vehicles shall be inspected in an as-received condition.

II.G.2. The inspection shall be performed with all accessories off.

II.G.3. The appropriate emissions limits as specified in Part F of this regulation shall be selected by the TAS based upon the model year and vehicle classification.

II.G.4. Light-duty vehicles found to be safe but unable to be dynamometer tested shall be administered an idle short test as specified in 40 CFR, Part 51, Subpart S, Appendix B. Eligibility for an alternative test procedure shall be determined by the Division based upon:

II.G.4.a. The vehicle wheelbase greater than 125 inches

II.G.4.b. The vehicle wheelbase less than 92 inches

II.G.4.c. The vehicle driveline, traction control system, and/or brake system, which has not been modified from the original configuration, can not be accommodated on the dynamometer.

II.G.4.d. The vehicle is “Handicapped” plated and fitted with hand controls or similar apparatus to facilitate operation of the vehicle.

II.G.5. Heavy-duty vehicles to be inspected at licensed enhanced inspection centers within the enhanced program area shall be administered an appropriate EPA approved idle short test as specified in Section II (A) of this Part C.

II.G.6. The inspector may refuse to conduct the transient driving cycle dynamometer inspection procedure if the tires on the drive wheels are worn such that the cords are visible or sidewalls are peeling or blistered.

**III. EMISSIONS CONTROL SYSTEMS INSPECTION PROCEDURES**

The emissions mechanic or emissions inspector shall inspect model year 1975 and newer vehicles and assess the integrity of the emissions control systems. Motor vehicles shall be configured as required for sale or use within the United States pursuant to 40 CFR, Part 86, Subpart A; unless specific documentation in the form of a state issued vehicle evaluation form (DR 2365) or an EPA (EPA form 3520) or DOT exemption is submitted. The inspection shall include, based upon the TAS display of appropriate equipment:

III.A. Visually inspect for the presence and operability of the air system, catalytic converter(s) system(s), oxygen (O2) sensor(s) system, “check engine” dash indicator light, other emissions control system malfunction service-maintenance indicators), fuel filler neck restrictor(s) and gasoline cap(s). If these parts or systems are not operating as designed, inoperable, or have been

removed, the vehicle will not qualify for a Certification of Emissions Control. The absence or inoperability of the fuel filler neck restrictor system “Flapper Door” would not constitute a failure at the time of inspection.

III.B. In circumstances under which the systems/components specified above are not present, examine the emissions control information decal (sticker) within the engine compartment appropriate for that specific vehicle for a listing of manufacturer installed emissions control equipment to determine if the vehicle, as manufactured and/or certified for sale or use within the United States, contained a catalytic converter, air injection reaction system, oxygen (O2) sensor system, “check engine dash indicator light” and/or other emissions control system malfunction/service-maintenance indicators, or requires the use of unleaded fuel. The emissions mechanic or emissions inspector shall also refer to the certified TAS emissions control look-up table to verify application requirements. A vehicle's emissions control information decal always takes precedence over a reference look-up table.

Vehicles in which the emissions control information decals are missing, incomplete, are not appropriate to that specific vehicle, or are no longer legible are to be failed for the questionable system(s) and referred to a state operated emissions technical center or technical assistance lane for an evaluation. Pending the results of an evaluation by emissions technical center personnel or designee, a supplemental inspection document, “AIR Program Vehicle Evaluation” (DR2365) may be issued further clarifying specific emissions control inspection requirements for the specific vehicle in question. This information is to be followed by the emissions inspector or emissions mechanic.

III.C. Assessment of System Malfunction/Service Indicators

An assessment of the emissions control system malfunction/service-maintenance indicator(s) performance shall be conducted by the emissions mechanic or emissions inspector on those vehicles so equipped.

For those vehicles equipped with “check engine” dash indicator lights or similar emissions control systems malfunction or service-maintenance indicator(s), the following procedure if applicable will be performed to assess the integrity of the system:

- Ignition Off, Engine Off = indicator(s) off

- Ignition On, Engine Off = indicator(s) on or displayed

- Ignition On, Engine Running = indicator(s) off

The revisions to the malfunction indicator light emissions test criteria contained in Section III.C. and adopted by the Commission on October 17, 2002 shall take effect on April 1, 2003. Thereafter, the failure of the system to respond as described above shall be reported to the motorist, but shall not be used to fail the vehicle.

Light-duty vehicles to include light-duty trucks of model year 1996 and newer equipped with California on-board diagnostic (OBDII) or EPA on-board diagnostic systems (EPA, OBD) shall be evaluated to determine operability and integrity of the applicable system(s). The OBD system will be connected to the TAS and interrogated. Fault codes and diagnostics shall be reported to the motorist with other emissions inspection information but shall not be used to fail the vehicle.

III.D. If the vehicle failed the initial inspection for the fuel filler neck restrictor inspection, the fuel filler neck restrictor(s) must be replaced.

The repair/replacement of catalytic converters must incorporate the same type, style and location

on the exhaust system relative to engine as originally designed by the vehicle manufacturer. If a new original equipment manufacturer (OEM) part is not used, only an EPA “accepted” after-market component appropriate to that application may be used. Verification of the correct application and certification status must be performed at the time of reinspection. The submittal and review of repair receipts as specified in subsection VII.B of this section is required in order to substantiate proper repairs of applicable emissions control system.

III.E. If the necessary part(s) will not be available prior to the month of expiration of the present vehicle registration, and the owner obtains a signed form or statement to that effect from a manufacturer's dealer for that make vehicle, or from an automotive parts supplier which in the normal course of business supplies part(s) for that vehicle, Department of Revenue personnel after verification may issue a temporary Certification of Emissions Control. The form or statement provided must specifically identify by part numbers and description, the necessary part(s). The owner then has until the expiration of the temporary certification to complete the necessary repairs or replacement.

**IV. EVAPORATIVE FUEL CONTROL INSPECTION PROCEDURES**

Model year 1975 and newer vehicles shall be inspected for the presence and integrity of the gasoline cap(s). The gasoline cap(s) of such vehicles inspected in the six county metro Denver enhanced program area as defined in Section 42-4-304(9)(a)., shall also be inspected for sealing integrity as specified in Part F (IV) of this regulation.

Vehicles with a missing gasoline cap(s) shall not qualify for issuance of a Certificate of Emissions Control. Motorists whose vehicles have gasoline cap(s) demonstrating excessive leakage shall be notified of the deficiency, repair/replacement shall be voluntary. Repair/replacement of defective cap(s) shall be required on and after January 1,1999. The gas cap sealing integrity procedure shall be effective January 1,1998.

**V. DETECTION OF CHLOROFLUOROCARBONS**

V.A. All pre 1995 model year vehicles equipped with passenger compartment air conditioning systems shall be inspected for chlorofluorocarbons (CFC) leakage.

V.B. Chlorofluorocarbon detection will be performed with leak detection equipment designated by the Division.

V.C. The Division shall designate any equipment reasonably designed to detect CFC.

V.D. The CFC leak detection procedure will be limited to the vehicle engine compartment and include but not limited to such components as the compressor, condenser, receiver/dryer (accumulator) and associated lines and hoses.

V.E. Motorists are to be notified of any detection of CFC leakage within the vehicle engine compartment.

V.F. Repairs to correct CFC leakage are voluntary.

**VI. FREE REINSPECTION**

Vehicles which fail any or all elements of an emissions inspection are eligible for one free reinspection within ten (10) calendar days if presented to the same station or facility as initially inspected and failed. In the case of the contractor operated enhanced inspection center network, the ten (10) day free reinspection shall be honored at any enhanced inspection center.

**VII. REPAIR INFORMATION**

Any after-repairs reinspection of a vehicle initially failed calls for the submittal of a completed official AIR Program emissions repair form.

**VIII. CERTIFICATION OF EMISSIONS CONTROL**

In order to obtain a Certificate of Emissions Control, the vehicle must meet the following conditions:

VIII.A. Certification of Emissions Compliance may be issued if:

VIII.A.1. The vehicle emissions levels are the same as or less than the applicable emissions limits; and

VIII.A.2. There are no smoke emissions visible from the vehicle engine crankcase and/or tailpipe, and

VIII.A.3. For 1975 and newer model year vehicles, the vehicle passes the emissions control systems inspection, and

VIII.A.4. Under enhanced inspection requirements, the vehicle owner/operator of a 1995 or newer model year vehicle shall demonstrate compliance with any federal emissions recall-pursuant to 40 CFR Part 85.1902 (d) or remedial repair plan pursuant to Section 207 (C) of the federal Clean Air Act for which owner notification occurs after 01 January 1995.

VIII.B. A Certification of Emissions Waiver may be issued if:

VIII.B.1. The vehicle passes the emissions control systems inspection (1975 and newer model year vehicles only) required by subpart III. A, B and C.; and

VIII.B.2. Basic Program: Effective January 1,1995

For model year 1981 and earlier at least seventy-five dollars ($75) has been spent on emissions related adjustments and repairs as specified in subpart IX and X provided that proof of repair costs for that specific vehicle has been provided to Department of Revenue personnel or designee in the form of an itemized bill, invoice, work order, manifest, or statement in which emissions related parts and/or repairs, are specifically identified.

For model years 1982 and newer, at least two hundred dollars ($200) has been spent on emissions related adjustments and repairs as specified in subpart IX and X, provided that proof of repair costs for that specific vehicle has been provided to Department of Revenue personnel or their designee in the form of an itemized bill, invoice, work order, manifest, or statement in which emissions related parts and/or repairs, are specifically identified.

VIII.B.3. Enhanced Program: Effective January 1,1995

For model year 1968 and newer, at least four hundred and fifty dollars ($450) or as adjusted annually by the Consumers Price Index for Urban Consumers (CPIU) of the previous year as compared to 1989 has been spent on emissions related adjustments and repairs as specified in subpart IX and X, provided that proof of repair costs for that specific vehicle has been provided to Department of Revenue personnel or their designee in the form of an itemized bill, invoice, work order, manifest, or statement in which emissions related parts and/or repairs, are specifically identified. The Division shall adjust the amount that must be expended by the motorist in order to qualify for a

Certificate of Emissions Waiver, which amount shall be established for each calendar year through 2004 by the Division pursuant to the criteria specified in Section 42-4-310(1)(d)(VI),C.R.S.

For model year 1967 and earlier at least seventy-five dollars ($75) has been spent on emissions related adjustments and repairs as specified in subpart IX and X provided that proof of repair costs for that specific vehicle has been provided to and verified by the emissions inspector in the form of an itemized bill, invoice, work order, manifest, or statement in which emissions related parts and/or repairs, are specifically identified.

If no emissions reduction is achieved, the motorist is to be referred to the Department of Revenue or its designee pursuant to Sections IX. G. and X. of this Part C.

VIII.B.4. An emissions reduction as determined by the Division-approved COLO'94 Test Analyzer System has resulted due to emissions related repairs and the applicable cost limit has been met. Proof of these emissions related repairs is required and to be retained by the AIR Program station, facility or center until purged by state program personnel. The vehicle must have passed the emissions control systems inspection and there are no smoke emissions visible from the vehicle engine crankcase or exhaust system.

VIII.B.5. Engine operational parameter verification.

VIII.B.5.a. All engine parameter adjustments for idle speed, proper air/fuel ratio and cold enrichment, as well as proper ignition dwell and timing (if applicable), have been set to or verified as being set to manufacturers specification by a licensed mechanic or registered repair facility/technician.

VIII.B.5.b. For those 1981 and newer vehicles equipped with computer based, engine management systems, also known as closed loop, feedback controls shall have the following additional sensors/systems verified to be operating within vehicle manufacturer specifications.

VIII.B.5.b.(1) As applicable to the vehicle being inspected, the oxygen sensor, throttle position sensor, coolant temperature sensor, manifold absolute pressure sensor.

VIII.B.5.b.(2) The engine management control system will be scanned for default/malfunction codes with those systems or components identified corrected.

VIII.B.5.b.(3) Primary and secondary ignition system integrity shall be verified for correct operation.

VIII.B.5.b.(4) A fuel delivery system utilizing a carburetor will be inspected for leaks, idle speed control adjustments, float operation and cold enrichment. A fuel delivery system utilizing fuel injection be it throttle body or multiport configuration, shall be checked for injector function, cold enrichment and injector spray patterns. Fuel injectors shall also be evaluated for proper volume and injection pulse width. Fuel system pressure shall be checked for residual and running pressure.

VIII.B.5.b.(5) A cylinder leakdown procedure shall be performed on all cylinders of the engine with the results reported to the motorist.

VIII.B.5.b.(6) With the exception of item (5) above, component/system

deficiencies found to be out of manufacturer's operational specification(s) will be corrected. The cost of such repairs shall be creditable towards issuance of a waiver.

VIII.C. If in the opinion of a registered emissions repair facility/technician, a vehicle which is properly adjusted to all manufacturers emissions related specifications and all emissions control systems appear to be operating as required, yet the vehicle continues to exceed one or more emissions limits and the repair expenditure limits have not been met, a waiver shall be issued upon physical verification of systems operation and vehicle performance by emissions technical center personnel.

VIII.D. Upon verification by a Department of Revenue Motor Vehicle Emissions Compliance Inspector, a waiver not to exceed one inspection cycle may be granted to obtain necessary emissions related repairs on a vehicle in the case of economic hardship when the Certificate of Emissions Waiver requirements of this section have not been met. It must be verified that the vehicle owner in question is participating in an established and recognized public assistance program as adopted by the Department of Revenue. The provisions of this paragraph D shall only apply to a vehicle once. In order to apply, the motor vehicle owner shall also comply with those applicable regulations of the Department of Revenue.

VIII.E. A Certificate of Emissions Waiver will not be issued to a vehicle which is eligible for the Emissions Control Systems Performance Warranty, 207(b) of the federal Clean Air Act. Per the provisions of the 207(b) Performance Warranty, the repair costs necessary for compliance with AIR Program emissions limits specified in Part F of this regulation will be borne by the vehicle manufacturer or his authorized dealer representative.

VIII.F. The emissions mechanic or emissions inspector shall generate the appropriate vehicle inspection report forms, electronic records, Certificate of Emissions Control, as required by the Department of Revenue or the Division and distribute to the motorist and the Departments of Health and Revenue. The emissions mechanic or emissions inspector will remove all expired Verification of Emissions Test windshield stickers. The vehicle inspection report is to be electronically identified by the issuing emissions mechanic or emissions inspector.

**IX. ADJUSTMENT PROCEDURES**

The emissions mechanic is to secure high altitude specifications for idle speed, idle mixture, ignition timing, dwell, and fast idle speed for the purpose of adjustment. If no high altitude specifications are available through the Department of Health or other reference sources refer to the emissions decal, other applicable specifications guide, or sea level specifications for proper specifications.

IX.A. With a dwell meter, check to determine if the ignition dwell is within the recommended tolerance of ±2° of specifications. Reset if the ignition dwell is not within tolerance.

IX.B. Connect tachometer to determine if idle speed is correct. If not, set to manufacturer's specifications with a tolerance of ±50 rpm.

IX.C. With the engine idling at the correct speed, check ignition timing to determine if it is within +4° to -2° of the recommended setting, if no high altitude specifications are available.

IX.D. Using an infrared analyzer, propane enrichment kit, and/or tachometer, adjust the idle air/fuel ratio using manufacturer's suggested procedures and specifications, if applicable.

IX.E. After completing the preceding steps, readjust idle speed to manufacturer's specifications, if not within tolerance.

IX.F. Using the manufacturer's suggested procedure, check the fast idle speed and adjust to manufacturer's specifications.

IX.G. If the vehicle continues to exceed applicable emissions limits, the vehicle must undergo specific emissions related adjustments and repairs. Adjustments and repairs must be accomplished to the point of compliance, or the applicable cost ceiling must have been met. If the applicable emissions related adjustment and repair requirements have been met but an emissions reduction has not resulted, the vehicle owner may be referred to a Department of Revenue Motor Vehicle Emissions Compliance Inspector to get a waiver. Repairs must have been reasonably calculated to achieve a reduction in emissions of those components of the inspection the vehicle failed, pursuant to manufacture's specifications as required by Sections 42-4-306(7)(a)(II)(A) and 42-9-111,C.R.S.

**X. EMISSIONS RELATED REPAIRS**

X.A. Emissions related repairs generally include only those adjustments to and maintenance and repair of the motor vehicle which are directly related to the reduction of exhaust emissions necessary to comply with the applicable emissions limits and procedures. The expenditure for emissions related repairs does not include the inspection fee as specified in Section 42-4-311, C.R.S. or expenses associated with the adjustments to and maintenance, replacement, and repair of air pollution control equipment on the vehicle if the need for such adjustment, maintenance, or repair pursuant to subpart III is due to disconnection of, tampering with, or abuse to such air pollution control equipment. Air pollution control equipment is any part, assembly or system originally installed by the manufacturer for the sole or primary purpose of reducing emissions.

X.B. Repairs and maintenance to the following systems shall qualify as emissions related repairs insofar as the purpose is to reduce exhaust emissions:

- Air Intake Systems
- Ignition Systems
- Fuel Control Systems
- Emissions Control Systems
- Basic Engine Systems
- For microprocessor ($O_2$) based air/fuel control systems, cooling systems.

X.C. Within the basic program, emissions related adjustments and repairs must have been performed by a licensed emissions mechanic or repair facility/technician registered with the Division pursuant to Part D of this regulation in order to be creditable to the repair cost waiver limits.

In order to be creditable to the enhanced repair cost limits, adjustments and repairs must have been performed by a repair facility/technician registered with the Division pursuant to Part D of this regulation.

Only the appropriate emissions failure related parts costs shall apply to applicable waiver limits for repairs not performed at a licensed emissions inspection station or registered repair facility/technician.

**XI. ENGINE CHANGES**

XI.A. For those vehicles in which the original engine has been replaced, the emissions limits and

applicable emissions control equipment for the year and model of the vehicle body/chassis, as per registration/title or replacement engine, whichever is newest, shall apply. For those diesel powered vehicles which have been converted to operate on fuel(s) other than diesel; the emissions limits and applicable emissions control equipment for the year, make and model of the gasoline powered engine equivalent as originally manufactured, for the vehicle body/chassis, per the registration or replacement engine, whichever is newest, shall apply as determined by emissions technical center personnel or designee and specified on an official AIR Program vehicle evaluation form (DR2365).

XI.B. For 1975 and newer vehicles in which the original engine has been replaced, if either the vehicle body/chassis original engine, as per registration/title or replacement engine as manufactured had a catalytic converter system, air injection reaction system, microprocessor based air/fuel control system, and/or fuel filler neck restrictor(s), these emission control systems must be present, intact and operational before a Certification of Emissions Control may be issued.

XI.C. For those vehicles titled/registered as model year 1975 and newer, that were assembled by other than a licensed manufacturer such as kit-cars, registered/titled according to Section(s) 42-6-108 and/or 42-5-205, C.R.S. and assigned a state or manufacturer specific identification number, the applicable emissions control equipment and standards will be based upon a determination by technical center personnel of the vintage of the vehicle engine. An affidavit may be issued by the technical center personnel and the year of the engine shall be presumed to be that stated by the vehicle owner unless it is determined by state emissions technical center personnel or designee, after physical inspection of the vehicle engine, that the year of the engine is other than stated by the owner.

**XII. CLEAN SCREEN INSPECTION PROGRAM PROCEDURES**

XII.A. Eligibility to participate

XII.A.1. Vehicles specified in Part A, Section IV.B., are eligible for participation in the Clean Screen Program.

XII.A.2. Clean Screen inspections applicable to the program are those performed within twelve months prior to an individual vehicle's registration renewal date.

XII.A.3. Vehicles are eligible for participation in the Clean Screen Program when the two most recent consecutive emissions readings observed during the 12-month period of time specified in item 1 of this subsection comply with the standards specified in Part F (VI) and: the most recent passing emissions reading occurred on a different day or at a different site location from the prior reading.

XII.A.4. The following vehicles are ineligible for participation in the Clean Screen Program:

XII.A.4.a. New Vehicles as specified in Section 42-4-310(b)(II)(A), C.R.S.

XII.A.4.b. Vehicles involved in a change of ownership.

XII.A.4.c. Vehicles owned by the United States government or any agency thereof or by the State of Colorado or any agency or political subdivision thereof, pursuant to Section 42-4-310(I)(b)(I), C.R.S.

XII.B. All aspects of inspection must be performed by a licensed Clean Screen Inspector.

XII.C. Clean Screen Test Analyzer Systems

XII.C.1. Vehicles participating in the Clean Screen Program shall be tested as specified in this Part C utilizing a Clean Screen Test Analyzer System recognized by the Division as having complied with the performance and design requirements specified in Part B (IX) of this regulation.

XII.C.2. Clean Screen Test Analyzer Systems will be periodically calibrated and maintained as required in Part B (IX) of this regulation.

XII.C.3. The inspection data processing system(s) used by the Data Manger and Clean Screen Inspector will be that approved by the Division, and the Department of Revenue.

XII.D. Vehicle owners participating in the Clean Screen Program are not subject to the provisions of Part C (I) through (XI).

XII.E. Certification of Emissions Control.

In order to obtain a Certificate of Emissions Control the following conditions must be met:

XII.E.1. The vehicle emissions levels are the same as or less than the limits specified in Part F(VI).

XII.E.2. The most recent two consecutive emissions readings were observed within twelve months of the registration renewal date provided that the most recent passing emissions reading must have occurred on a different day or at a different site location from the prior reading.

XII.E.3. No non-complying emissions readings are observed between or subsequent to the last pair of complying readings.

**Part D Qualification and Licensing of Emissions Mechanics, Emissions Inspectors, and Clean Screen Inspectors; Licensing of Emissions Inspection and Readjustment Stations, Inspection-Only Stations, Inspection-Only Facilities, Fleets, Motor Vehicle Dealer Test Facilities, Enhanced Inspection Centers; Qualification of Clean Screen Inspection Sites; and Registration of Emissions Related Repair Facilities and Technicians**

**I. LICENSING OF EMISSIONS INSPECTION AND READJUSTMENT STATIONS, INSPECTION-ONLY STATIONS, INSPECTION-ONLY FACILITIES, ENHANCED INSPECTION CENTERS, FLEET INSPECTION STATIONS AND MOTOR VEHICLE DEALER TEST FACILITIES**

I.A. Emissions Site Requirements for the Licensing of Emissions Inspection and Readjustment Stations, Inspection-Only Stations, Inspection-Only Facilities, Fleet Inspection Stations and Motor Vehicle Dealer Test Facilities:

I.A.1. Applicability

All emissions inspection and readjustment stations, inspection-only stations, inspection-only facilities, fleet inspection stations, and motor vehicle dealer test facilities are required to meet all applicable standards pursuant to this Part D and the Department of Revenue's adopted regulations in order to qualify for licensing for operation in Colorado's AIR Program.

To achieve the uniformity and security needed in test site locations; in order to meet federal EPA regulations contained in Federal Register vol. 57, no. 215, of the Federal Register and meet the statutory requirements contained in Sections 42-4-301 through 42-4-316, C.R.S.; the Air Quality Control Commission adopts this standard for emissions site

requirements.

I.A.2. Standards for emissions inspection sites:

I.A.2.a. All facilities shall be a permanent type of structure.

I.A.2.b. All sites must be capable of receiving mail.

I.A.2.c. All test facilities shall have a minimum of two off-street parking spaces for staging to accommodate additional vehicles.

I.A.2.d. All test site facilities shall have a customer waiting area that provides for observation of the entire emissions inspection process. Observation can be, direct observation, observation by electronic equipment, or other methods that prove to be as effective with prior approval of the Department of Revenue.

I.A.2.e. All test sites shall be capable of conducting all aspects of the inspection process within the confines of a building or structure, and maintaining ambient air temperatures between 41 degrees and 110 degrees fahrenheit in the inspection area as defined in subpart I (C)(1) of Part C of this regulation. Inspections are not required to be performed within the confines of a structure or building provided ambient temperatures are within such parameters.

I.A.2.f. All test site facilities shall have an adequate exhaust removal system which shall be designed so as to not alter the inspection results and to assure safe ambient air quality of the inspection area as established by the Occupational Safety and Health Administration pursuant to 29 CFR, Part 1910, subpart Z.

I.A.3. Pursuant to Sections 42-4-306(4)(a) and 42-4-307 (8)(a), C.R.S. as amended, the Division shall develop or contract for the development of a training program for emissions mechanics and emissions inspectors. The training program shall be comprehensive in nature and address all aspects of vehicle inspection procedures specified for this regulation.

I.A.3.a. Participation by emissions inspectors intending to operate in the enhanced program area shall be required.

I.A.3.b. Participation by emissions mechanics intending to operate in the basic program area shall be voluntary.

I.A.3.c. Training classes shall be funded by tuition charged to the participants.

I.A.3.d. The following tuition rates and fees shall apply

I.A.3.d.(1) The training class fee shall be no greater than $150 per participant.

I.A.3.d.(2) The instructor's fee for presenting a class shall not exceed $400.

I.A.3.d.(3) The training manual for those emissions mechanics who choose not to participate in a training class shall be no greater than $25.

I.A.3.e. These same training provisions shall be applicable to the requalification provisions of subpart II.B. of this Part D.

I.B. The following tools, reference manuals and diagnostic equipment shall be available for performance

of inspections; and within the basic program, emissions related adjustments and repairs.

I.B.1. Division approved calibrated and spanned Test Analyzer System (TAS).

I.B.1.a. As a provision of continued license to perform AIR Program inspections, the TAS must be updated as required, pursuant to this regulation.

I.B.1.b. The station or facility owner or operator shall maintain a full service/maintenance contract with the equipment manufacturer or equipment manufacturer's designee valid for the duration of the program but renewable on an annual basis

I.B.2. Rules for the operation of AIR Program inspection stations provided by the Colorado Department of Revenue.

I.B.3. Tachometer capable of reading 4,6 and 8 cylinders, 0-6,000 RPM minimum at no greater than 10 RPM of actual speed.

I.B.4. Emissions control systems applications guide as incorporated into the TAS, and oxygen sensor/check engine light, systems maintenance guide in either printed or electronic medium.

I.B.5. Dwell meter.

I.B.6. Ignition timing light.

I.B.7. Propane enrichment kit for idle mixture adjustment and diagnostics.

I.B.8. Commercially available reference manuals giving idle speed, idle mixture, mixture control dwell or fuel injection duration, timing, dwell, fast idle speed specification, high altitude specifications and information covering the emissions control systems description, diagnostic and repair procedures for the year models of vehicles involved in the AIR Program. In either printed or electronic medium.

I.B.9. Sufficient hand tools including but not limited to suitable computer scanner diagnostic link, digital volt/ohm meter, vacuum pump and other automotive diagnostic equipment for proper performance of the inspections, adjustments and emissions related repairs as applicable to the licensed entity.

I.B.10. Division approved span gas and equipment for performing gas span checks and calibrations.

I.B.11. Suitable non-reactive tail pipe extenders or probe adapter for inspecting vehicles with screened or baffled exhaust systems, or exhaust systems with multiple tail pipes.

I.B.12. The analyzer manufacturer's maintenance and calibration manual must be retained in the inspection area.

I.B.13. A Division approved, calibrated and spanned chlorofluorocarbon detection device.

I.B.14. Items #5, 6, 7, 8 and 9 above are not required for licensing as an inspection-only station or inspection-only facility.

I.C. A licensed emissions mechanic or emissions inspector who has successfully completed a hands-on proficiency check administered by the Department of Revenue in accord with the Commission regulations and those of the Department of Revenue, and the criteria specified in Part D of this

regulation is or will be available to make a proper inspection. Enhanced inspection centers shall be open 8:30 am - 7:30 p.m. weekdays, and Saturday 8:00 a.m. -1:00 p.m.

I.D. An emissions inspection-only station and inspection-only facility, must so indicate same by posting a sign in a readily visible location, and that no emissions related adjustments or repair services are available should the vehicle fail the inspection procedure.

I.E. A person to whom there are twenty (20) or more vehicles registered, or to whom said number of vehicles are leased for not less than six continuous months, or are consigned for sale, may be licensed as a "fleet inspection station" or as a dealer licensed under Article 6 of Title 12, C.R.S., a motor vehicle dealers test facility and conduct inspections of that fleet or those vehicles inventoried or consigned for retail sale. As a fleet inspection station or motor vehicle dealer test facility, no inspections may be conducted for the employees nor general public, but only on vehicles owned, leased by the business, or consigned or held in inventory for sale. A Certificate of Emissions Control issued by a fleet emissions inspection station will be valid for 12 months, one vehicle registration cycle.

I.E.1. Under the self-inspection provisions of Section 42-4-309, C.R.S. for fleets of twenty (20) or more vehicles, the retail sale of a fleet vehicle within the enhanced program area requires full compliance with applicable inspection procedures as performed by an enhanced inspection center or an (enhanced) inspection-only facility.

I.E.2. At the time of initial licensing and annually thereafter, the vehicle fleet shall be declared by completing a listing of all eligible vehicles by make, model year, light-heavy duty classification, vehicle identification number, license plate number, and if applicable unit number and state of registration on forms provided by the Division.

I.F. All AIR Program inspection stations, facilities and centers are required to post in a conspicuous location in a clearly legible fashion a sign indicating the fees charged for inspections and in the basic program area, and maximum fees for emissions related adjustments and repairs required for the issuance of a Certificate of Emissions Control.

I.G. All AIR Program inspection stations, facilities and centers are required to be linked via dedicated service line to the program data/communications network.

I.G.1. Basic program inspection services providers and independent inspection-only facilities in the enhanced area shall be linked to the data network via dedicated voice quality telephone lines with a dial-up back-up telephone line.

I.G.2. Enhanced inspection centers shall be linked via dedicated data quality lines with dedicated voice quality lines as dial-up back-up.

I.H. All sites must provide for reasonable access in order for Departments of Revenue (or if applicable, Health) staff to conduct periodic quality control and audit functions as necessary.

I.I. Upon request for a license as an emissions inspection and readjustment station, inspection-only station, fleet inspection station, motor vehicle dealer test facility, or inspection-only facility, applicants shall complete forms approved by the Department of Revenue which shall include but not be limited to a declaration of any past violations of AIR Program statute Section 42-4-301 through 42-4-316, C.R.S. as amended or any rule or regulation pursuant to such law.

## II. QUALIFICATION AND LICENSING OF EMISSIONS MECHANICS, AND EMISSIONS INSPECTORS

II.A. Qualification of Emissions Mechanics and Emissions Inspectors

II.A.1. Application for qualification as an emissions mechanic and emissions inspector shall be filed with the Air Pollution Control Division. Issuance of letters of qualification shall be administered by the Division. Applications for such letters of qualification shall be completed on forms provided by the Division. Before an applicant may be given a letter of qualification, he must comply with the requirements of this section II. The Division will notify applicants of the evaluation requirements prior to testing.

II.A.2. An applicant must demonstrate knowledge, skill, and competence concerning the conduct of emissions inspections, and within the basic program area the adjustment and repair of vehicles to manufacturers' specifications. Such knowledge, skill and competence will be shown by passing a written and skills proficiency qualification test including, but not limited to, knowledge of the following:

II.A.2.a. Operation and purpose of emissions control systems.

II.A.2.b. Relationship of exhaust and evaporative HC and CO to timing and air/fuel ratio control.

II.A.2.c. Adjustment and repair to manufacturers' and applicable high altitude specifications.

II.A.2.d. Rules and regulations of AIR Program and proper inspection procedures.

II.A.2.e. Contemporary diagnostic and engine tune-up procedures.

II.A.2.f. The provisions of the Emissions Control Systems Performance Warranty pursuant to Section 207 (A) and (b) of the federal Clean Air Act as it applies to the AIR Program.

II.A.2.g. Visual inspection of the required emissions control equipment for 1975 and newer vehicles.

II.A.2.h. Operation of and proper use, care maintenance, calibration and gas span checking of the Division-approved inspection equipment.

II.A.2.i. Proper use of, security, and distribution of inspection forms, Certificates of Emissions Control, and supplemental inspection documents.

II.A.2.j. Emissions related adjustment and repair requirements for all vehicles failing the initial emissions inspection.

II.A.2.k. Inspecting for visible smoke emissions.

II.A.2.l. Inspecting for chlorofluorocarbon (CFC) emissions.

II.A.2.m. Cause and effect of air pollution.

II.A.2.n. Purpose, goal and function of the AIR Program.

II.A.2.o. Exhaust and evaporative emissions inspection procedures and rationale for use.

II.A.2.p. Public relations and motorist assistance.

II.A.2.q. Safety procedures in the inspection lane or bay.

II.B. Requalification Requirements for all Emissions Mechanics and Emissions Inspectors

II.B.1. Upon the determination by the Commission of the necessity of technically updating the qualifications for emissions mechanics or emissions inspectors and, upon development or approval of retraining courses and retesting requirements for emissions mechanics to demonstrate said qualification, emissions mechanics, or holders of certificates of qualification, shall be required to requalify biennially.

II.B.2. Emissions mechanics and emissions inspectors shall be required to requalify within ninety (90) days from the date of written notification by the Department of Revenue. Said notice shall be mailed to the address of record in the office of the Department of Revenue charged with licensing of emissions mechanics and inspectors, which notice shall inform the person of the necessity of requalification and the nature of such skills, systems, and procedures requiring the retraining for the continued performance of the emissions inspection. The notice shall give the name and location of training sources approved or accredited for purposes of retraining, the necessity of requalification by a certain date, and the nature and evidence of documentation to be filed with the Department of Revenue evidencing such requalification, and state that failure to requalify within said period of time shall result in suspension or revocation of the emissions mechanic's or emissions inspector's license or certification as described in the Department of Revenue rules and regulations.

II.B.3. The Division shall issue a letter of requalification to any person who has requalified to the satisfaction of the Division and according to the requalification regulation of the Department of Revenue.

II.C. Transmittal of Letters of Qualification and Issuance of Emissions Mechanic's and Emissions Inspector's Licenses

The Division shall provide a listing of all letters of qualification or letters of requalification for emissions mechanics or emissions inspectors to the Department of Revenue, and, upon application by any person qualified, the Department of Revenue shall issue an emissions mechanic's or emissions inspector's license or renewal license in accord with the regulations of that department.

II.D. Lapse of Certificate of Qualification for Emission Mechanic.

A person to whom the Division has issued a letter of qualification, who has not been issued an emissions mechanic's or emissions inspector's license within six (6) months from the date of issuance of the most recently issued letter of qualification shall be deemed to have forfeited said qualification and shall be required to reapply if a new letter of qualification is requested.

II.E. Program License Application Performance Review Criteria

II.E.1. Applicability

Pursuant to Sections 42-4-306(4)(c) and 42-4-308(1 )(b), C.R.S. the Commission is authorized to establish minimum performance criteria for licensed emissions inspectors, mechanics, and stations. Based on these performance criteria, Section 42-4-312, C.R.S. grants authority to the Executive Director of the Department of Revenue to suspend or revoke a license on a finding of a pattern of violations.

In order to meet federal act requirements and to provide a consistent criteria for the Department of Revenue's review of performance based evaluations that may result in a denial of the license application, the Executive Director of the Department of Revenue or

the designee shall apply criteria contained in this section E.

II.E.2. Standards

The following criteria shall be used by the Department of Revenue's Executive Director or his designee in the review of any emissions license application for a mechanic, inspector, inspection and readjustment station, inspection-only station, inspection-only facility, fleet station, or motor vehicle dealer test facility.

Performance

Based on violations and penalties provided in Section 42-4-313(4)(b)(1), C.R.S. the following criteria will be used for the review of any emissions license application listed in this section:

II.E.2.a. Any substantiated violation of intentional passing of a failing vehicle.

II.E.2.b. Any substantiated violation of performance of emissions tests by an unlicensed mechanic, inspector, or station.

II.E.2.c. Any substantiated violation of performance of an emissions test on falsified emissions test equipment.

II.E.2.d. Any substantiated violation of failing of passing vehicles.

II.E.2.e. Any substantiated violation of flagrant misuse of emissions program control documents.

II.E.2.f. Any substantiated pattern of non-compliance with AIR Program regulations.

II.E.2.g. Any substantiated violation of false statements on any emissions license application in an attempt to conceal problems such as: administrative hearings held for program violations, any probation of any emissions license held previously or currently held, any suspension or revocation of any emissions license held previously or currently.

For the purposes of emissions license application review, past performance may entail complete program history review of any person, persons, or officers of a corporation, or partners of any partnership that hold or held a license with the AIR Program.

II.E.2.h. As a prerequisite to licensing of an emissions mechanic or emissions inspector, a hands-on proficiency check to address the criteria described in section II. A. 2. of this Part D will be administered by the Department of Revenue in accord with the regulations of the Commission. This evaluation will be conducted at the emissions mechanic's or emissions inspector's place of employment and on an exhaust gas analyzer or test analyzer system that would be used to conduct inspections.

In order to provide for continuity and consistency with training, testing and licensing activities conducted per this Part D, the development and maintenance of the hand-on proficiency check will be coordinated between the Department of Revenue and the Division.

## III. REGISTRATION OF EMISSIONS RELATED REPAIR FACILITIES

III.A. Automotive Emissions Related Repair Facilities May Voluntarily Register with the Division.

III.A.1. The repair facility/technicians agree to have the effectiveness of their emissions related repairs and repair costs monitored by the Division on an on-going basis.

III.A.2. Repair facility/technicians agree to having repair effectiveness listing provided to those motorists whose vehicles fail any element of the inspection procedures specified in Part C of this regulation.

III.A.3. The facility shall complete and process AIR Program repair report forms as approved by the Division. Repair report form processing equipment may incorporate PC based bar code technology such that one dimensional 3of 9' and two dimensional "PDF 417" symbology can be read and written. The system must be capable of supporting form generation software provided by the state. The printer shall be an ink jet printer or equivalent capable of printing the bar code symbology stated. Refer to section 2.14 of the TAS specifications attached as Appendix A of this regulation for microcomputers specifications. Performance equivalence shall be determined by the Division.

III.B. As an aid to motorists seeking emissions related repair assistance, a means will be established whereby a listing of registered repair facilities whose repair effectiveness would be made available and presented to the motorist at the time of inspection failure. Repair effectiveness shall include but may not be limited to:

a. Number of vehicles repaired and retested

b. Percent passing on first retest

c. Percent requiring additional repairs and retests

d. Percent issued waivers

The listing shall document any recognized professional automotive accreditation or memberships which may include but not be limited to the National Institute for Automotive Service Excellence, or Automotive Service Association. The listing may also indicate the vehicle make(s) or vehicle classification that the repair facility specializes in.

III.C. Repair facilities may request removal form the listing or temporary placement on an inactive listing while measures are being taken to improve repair effectiveness.

III.D. It is further suggested that:

III.D.1. The repair facility/technicians will seek out appropriate training when repair effectiveness deficiencies are identified.

III.D.2. Repair facilities will hire and retain technicians certified under "Automotive Service Excellence" tests number A-1, A-6, A-8, and L-1 and that technicians will maintain these levels of certifications.

Ill.D.3. That the repair facility be adequately equipped and maintain a level of diagnostic and repair equipment necessary to perform emissions related repairs based upon the criteria set forth by the Automotive Service Association of Colorado, Incorporated.

III.D.4. The Department of Revenue perform a site evaluation of facilities which apply to assess compliance and confirm qualifications.

III.D.5. The facility has or could comply with the provisions established in Part D of this regulation and have not been subject to the penalties prescribed by Section 42-9-111, C.R.S.

III.E. The Division will monitor and periodically report to individual repair facilities their repair effectiveness and average costs as compared to other registered repair facilities.

III.F. The Division shall make repair effectiveness data available to the general public upon request as well as periodically to the Department of Revenue.

III.G. The Division may request a site evaluation of any registered repair facility by the Department of Revenue for reasons of diminished repair effectiveness or noted consumer complaints.

III.H. The Division shall identify the level(s) of repair effectiveness that would result in inadequate emission(s) reductions and negatively impact consumer protection.

**IV. REQUIREMENTS FOR CLEAN SCREEN/REMOTE SENSING SITES**

IV.A. Applicability

Clean Screen Inspection Sites must meet all applicable standards pursuant to this Part D and the Department of Revenue's regulations in order to qualify for operating in Colorado's Clean Screen Program.

IV.B. Standards for emissions inspection sites

All sites shall comply with all applicable state and local codes/ordinances and maintain appropriate permits for that specific municipality and location.

IV.C. All Clean Screen Sites must provide reasonable access in order for Department of Revenue (and if applicable, Division) staff to conduct periodic quality control and audit functions as necessary.

IV.D. Applicants for a license as a Clean Screen Emissions Inspector shall complete forms approved by the Department of Revenue which shall include, but not be limited to, a declaration of any past violations of AIR Program statute Sections 42-4-301 through 42-4-316, C.R.S., as amended or any rule or regulation pursuant to such law.

**V. QUALIFICATION OF CLEAN SCREEN EMISSIONS INSPECTORS**

V.A. Clean Screen Emissions Inspector applicants shall apply for letters of qualification on forms provided by the Division. The Division shall issue letters of qualification to applicants who comply with the requirements of this section V. The Division will notify applicants of the evaluation requirements specified in subsection B. below prior to testing.

V.B. An applicant for a letter of qualification or requalification must demonstrate knowledge, skill, and competence concerning the operation of Clean Screen emissions inspections. Such knowledge, skill and competence will be demonstrated on actual Clean Screen equipment and by passing a skills proficiency qualification test including, but not limited to, knowledge of the following:

V.B.1. Operation of and proper use, care, maintenance, calibration and gas span checking of the Division-approved Clean Screen Test Analyzer System.

V.B.2. Safety procedures for the Clean Screen Inspection Site.

V.B.3. Proper setup and breakdown of the Clean Screen equipment

## VI. REQUALIFICATION REQUIREMENTS FOR ALL CLEAN SCREEN EMISSIONS INSPECTORS

VI.A. Upon the determination by the Division of the necessity of updating the technical qualifications for Clean Screen Emissions Inspectors, holders of certificates of qualification shall be required to requalify biannually. The Division may waive this requirement should it be unnecessary.

VI.B. Clean Screen Emissions Inspectors shall be required to requalify within ninety (90) days from the date of electronic notification by the Department of Revenue.

VI.C. The Division shall issue a letter of requalification to any licensed Clean Screen Emissions Inspector who meets the requirements of section V.B.

## VII. TRANSMITTAL OF LETTERS OF QUALIFICATION AND ISSUANCE OF CLEAN SCREEN INSPECTOR LICENSES

The Division shall provide a listing of all letters of qualification or letters of requalification for Clean Screen Inspectors to the Department of Revenue, and upon application by any person qualified, the Department of Revenue may issue a Clean Screen Inspector's license or renewal license in accordance with the regulations of that department.

## VIII. LAPSE OF CERTIFICATE OF QUALIFICATION FOR CLEAN SCREEN INSPECTOR

A person to whom the Division has issued a letter of qualification, who has not been issued a Clean Screen Inspector license within six (6) months from the date of issuance of the most recently issued letter of qualification shall be deemed to have forfeited said qualification and shall be required to reapply if a new letter of qualification is requested.

## IX. PROGRAM LICENSE APPLICATION PERFORMANCE REVIEW CRITERIA

IX.A. Applicability

Pursuant to Sections 42-4-306(4)(c) and 42-4-308(1 )(b), C.R.S., the Commission is authorized to establish minimum performance criteria for licensed Clean Screen Inspectors and Data Management Contractor(s). Based on these performance criteria, Section 42-4-312, C.R.S., grants authority to the executive director of the Department of Revenue to suspend or revoke a license.

In order to provide consistent criteria for the Department of Revenue's review of performance based evaluations that may result in a denial of a license application, or revocation of a license, the executive director of the Department of Revenue or the designee shall apply criteria contained in Sections IV through VII of this Part D.

IX.B. Requirements

The following criteria shall be used by the Department of Revenue's executive director or his designee in the review of any emissions license application for a Clean Screen Inspector, or Clean Screen Data Manager.

Performance

Based on violations and penalties provided in Section 42-4-313(4)(b)(1), C.R.S., the following criteria will be used for the review of any license application listed in the section:

IX.B.1. Any violation of intentional passing of a failing vehicle.

IX.B.2. Any violation of performance of Clean Screen inspections by an unlicensed inspector, or at an unapproved/unlicensed site.

IX.B.3. Any violation of performance of a Clean Screen inspection on a falsified Clean Screened Test Analyzer System.

IX.B.4. Any violation of flagrant misuse of Clean Screen inspection data, control documents, vehicle owner information, or vehicle registration data.

IX.B.5. Any pattern of non-compliance with AIR Program regulations, including Clean Screen provisions.

IX.B.6. Any violation of false statements on any license application.

IX.B.7. As a prerequisite to licensing of a Clean Screen Inspector, a hands-on proficiency check to address the criteria described in Section V of this Part D will be administered by the Department of Revenue in accord with the regulations of the Commission. This evaluation will be conducted at a mutually agreed upon location and on an approved Clean Screen Test Analyzer System that would be used to conduct inspections.

In order to provide for continuity and consistency with qualifying and licensing activities conducted per this Part D, the development and maintenance of the hands-on proficiency check will be coordinated between the Department of Revenue and the Division.

**Part E Prohibited Acts and Penalties to Ensure Proper Inspection Procedures, Adherence to Prescribed Procedures and Effective Emissions Related Repairs**

**I. THIS PART E DESCRIBES THE GROUNDS UPON WHICH THE LICENSE OF AN EMISSIONS MECHANIC, EMISSIONS INSPECTOR OR ANY TYPE OF AIR PROGRAM INSPECTION BUSINESS MAY BE SUSPENDED, FOR A PERIOD OF TIME NOT LESS THAN SIX MONTHS, OR REVOKED.**

I.A. Pattern of Violations

The license of an emissions mechanic, emissions inspector, inspections and readjustment station, inspection-only station, inspection-only facility, fleet inspection facility, motor vehicle dealer test facility, or contractor's contract may be revoked or suspended, as appropriate pursuant to Sections 42-4-312 and, 42-4-313, C.R.S., if such mechanic, inspector or facility has engaged in a pattern of violations of the provisions of this Regulation 11, or other applicable statutes or regulations, including, but not limited to:

I.A.1. AIR Program inspection business, and/or emissions inspector or emissions mechanic is involved in any unauthorized entry into the analyzer or inspection system that results in a fraudulent inspection report and/or emissions certificate being issued.

I.A.2. AIR Program inspection business, and/or emissions inspector or emissions mechanic caused an inspection report and/or emissions certificate to be issued to a vehicle that did not at the time of issue comply with the laws, rules or regulations.

I.A.3. AIR Program inspection business, and/or emissions inspector or emissions mechanic makes, issues, or knowingly uses any imitation or deceptively similar or counterfeit inspection report and/or emissions certificate.

I.A.4. AIR Program inspection business, and/or emissions inspector or emissions mechanic possesses an inspection report and/or emissions certificate which is known to be

fictitious, or was issued for another vehicle, or was issued without an emissions inspection test having been performed when required.

I.A.5. Exercising licensing privilege other than those granted by the Department of Revenue and the Commission.

I.A.6. AIR Program inspection(s) have not or are not being made in accordance with applicable laws and the rules and regulations of the Department or the Commission.

I.A.7. Vehicles have not or are not being repaired in accordance with applicable laws and the rules and regulations of the Department or the Commission.

I.A.8. Emissions mechanic or emissions inspector failed to a post valid license.

I.A.9. AIR Program inspection business, and/or emissions inspector or emissions mechanic failed to post AIR Program license(s) in a location available and conspicuous to the public.

I.A.10. AIR Program inspection business, and/or emission inspector or emissions mechanic failed to use the correct inspection report form issued by the Department.

I.A.11. AIR Program inspection business, and/or emissions inspector or emissions mechanic used an inspection report form for a purpose other than permitted by the Department.

I.A.12. AIR Program inspection business, and/or emissions inspector or emissions mechanic failed to complete the correct inspection report form or,

I.A.13. AIR Program inspection business, and/or emissions inspector or emissions mechanic loaned, sold, gave or transferred inspection report forms to another AIR Program inspection business or mechanic.

I.A.14. Repealed.

I.A.15. AIR Program inspection business, and/or emissions inspector or emissions mechanic performed air tests with an analyzer or test system that was not certified.

I.A.16. AIR Program inspection business, and/or emissions inspector or emissions mechanic used span gas that was not approved.

I.A.17. AIR Program inspection business, and/or emissions inspector or emissions mechanic, failed to have tools, supplies and records available for inspection by the Department of Revenue.

I.A.18. AIR Program inspection business, and/or emissions inspector or emissions mechanic used “escape” mode in analyzer without valid reason.

I.A.19. AIR Program inspection business, and/or emissions inspector or emissions mechanic failed to properly identify and record a vehicle that fails the air test.

I.A.20. AIR Program inspection business, and/or emissions inspector or emissions mechanic failed to properly identify and record a vehicle that passes the emissions inspection.

I.A.21. AIR Program inspection business, emissions inspector or emissions mechanic falsely reports an (incorrect) vehicle identification number or vehicle information on a DR2411 form supplied by the Department of Revenue.

I.A.22. AIR Program inspection business, and/or emissions inspector or emissions mechanic performed inspections while under suspension or administrative hold.

I.A.23. AIR Program inspection business, and/or emissions inspector or emissions mechanic continued using an analyzer knowing it was malfunctioning.

I.A.24. AIR Program inspection business, emissions inspector or emissions mechanic charged more than posted fee for service.

I.A.25. AIR Program inspection business, through its agent denied the issue of a vehicle inspection report and/or Certificate of Emissions Compliance when at the time of inspection the vehicle did comply with the laws, rules and regulations for the issuance of such a certificate.

I.A.26. AIR Program inspection business was not open and available to perform inspection services during normal business hours.

I.A.27. AIR Program inspection business, through its agent, failed to issue a Certificate of Waiver to a vehicle that met all the requirements.

I.A.28. AIR Program inspection business, through its agent, issued a Certificate of Waiver to a vehicle that was eligible pursuant to Section 207(b) of the federal Clean Air Act

I.A.29. AIR Program inspection business, through its agent, performed repairs to the emissions control systems of a vehicle that are eligible for any manufacturer's warranties without informing the owner of said warranties.

I.A.30. AIR inspection business failed to display all required signs and post fees for inspection services.

I.A.31. Electrical supply fails to meet voltage and frequency requirements of 110V (±) 10% 60HZ, or is not publicly supplied as appropriate to that area.

I.A.32. AIR Program inspection business, through its agent, performed an inspection when the temperature of the inspection area was not between 41 degrees and 110 degrees fahrenheit.

I.A.33. AIR Program inspection business could not account for controlled documents.

I.A.34. Emissions mechanic or emissions inspector failed to keep their access code secure which resulted in an inspection conducted by an unlicensed person.

I.A.35. Emissions mechanic or emissions inspector failed to keep his current mailing address on file with the Department of Revenue.

I.A.36. A licensed emissions mechanic or emissions inspector is not employed at the facility.

I.B. Conditions Under Which a Station, Facility or Center License may be Denied, Suspended or Revoked.

In addition to the grounds listed in section A, the license of any inspection and readjustment station, inspection-only station, inspection-only facility, fleet inspection facility, motor vehicle dealer test facility or the Contractor, may be suspended or revoked as appropriate pursuant to Sections 42-4-312 and, 42-4-313, C.R.S. for any of the following violations:

I.B.1. AIR Program inspection business, and/or its agent has engaged in a pattern of violation of any provision of the applicable laws, rules or regulations.

I.B.2. AIR Program inspection business, through its agent issued a vehicle inspection report and/or Certificate of Emissions Waiver when at the time of issue the vehicle did not comply with the laws, rules and regulations for the issuance of such a certificate.

I.B.3. AIR Program inspection business, through its agent issued a vehicle inspection report and/or Certificate of Emissions Control without an air test having been performed.

I.B.4. Adjustments or repairs were performed when such adjustments or repairs were not authorized or required.

I.B.5. AIR Program inspection business is not equipped as required.

I.B.6. AIR Program inspection business was not operating from the location for which the license was issued.

I.B.7. Emissions mechanic or emissions inspector made false statements on official forms.

I.B.8. Facilities of applicant for an AIR Program license are not properly equipped for the type of license applied for.

I.B.9. The AIR Program inspection business flagrantly misuses control documents by committing any of the violations described in sections A.10, A.11, A. 12, A.13, or A.14 in a flagrant manner.

I.B.10. An unlicensed person performed all or any part of an inspection procedure.

I.B.11. Within the enhanced program area, Motor Vehicle Dealer Test Facility inspections are limited to one per vehicle (consecutively) such that no vehicle shall be inspected twice consecutively. Following an inspection at a Motor Vehicle Dealer Test Facility, that vehicle's inspection for the next cycle must be performed in the inspection-only network of enhanced inspection centers or decentralized inspection-only facilities; as applicable to the model year of the vehicle.

I.C. Conditions Under Which an Emissions Mechanic or Emissions Inspector License may be Denied, Suspended or Revoked.

I.C.1. Emissions mechanic or emissions inspector caused a passing Certificate of Emissions Compliance to be issued to a failing vehicle.

I.C.2. Emissions mechanic or emissions inspector made false statements on official forms.

I.C.3. The emissions inspector or emissions mechanic performed two or more emissions inspections using a test analyzer system that was not updated as required by Part B or Appendix A of this regulation.

I.D. Any action to suspend or revoke the license for any enhanced emissions center, or to revoke the contractor's agreement pursuant to this Part E, shall be subject to the terms of the agreement entered into pursuant to Section 42-4-304(5), C.R.S.

**Part F Maximum Allowable Emissions Limits for Motor Vehicle Exhaust, Evaporative and Visible Emissions for Light-Duty and Heavy-Duty Vehicles**

In order for a vehicle (owner) to obtain a Certificate of Emissions Compliance, the exhaust and evaporative emissions from the motor vehicle subject to an EPA approved emissions test as specified in Part C of this regulation may not exceed the applicable maximum concentrations or if applicable, maximum mass for exhaust carbon monoxide (CO), hydrocarbons (HC) and oxides of nitrogen (NOX); and the integrity requirements specified for fuel evaporation control and visible smoke.

**I. THE IDLE SHORT TEST CONCENTRATION LIMITS FOR LIGHT-DUTY VEHICLES AND HEAVY-DUTY TRUCKS SPECIFIED IN SECTIONS I (A) AND II (A) RESPECTIVELY OF THIS PART F ARE THOSE NECESSARY TO COMPLY WITH EMISSIONS REDUCTIONS AS THE PROGRAM MATURES.**

Subpart I (B) and II (B) establish maximum upper limits to aid in the transition to more stringent procedures. For all vehicles of model year 1981 and newer subject to idle short test(s), the emissions concentration limits of this subpart I shall also apply at raised idle speeds as specified in subpart II of Part C of this regulation.

The Division shall progressively adjust the emissions limits specified in subparts I.B. to I.A. and II.B. to II.A., only to the extent necessary to ensure a maximum 40% stringency rate for vehicles of model year 1981 and older as necessary to provide a gradual transition and comply with federal EPA requirements. The more stringent emissions limits shall be in effect no later than January 1,2000.

I.A. Maximum Concentration Limits for Light-Duty Vehicles (Includes Light-Duty Trucks) Subject to Idle Short Test(s) at Program Maturity

| Model Year | Percent Carbon Monoxide | Parts/million Hydrocarbon |
|---|---|---|
| 1970 and earlier | 3.5 | 1000 |
| 1971 | 3.0 | 1000 |
| 1972 | 3.0 | 1000 |
| 1973 | 3.0 | 1000 |
| 1974 | 3.0 | 1000 |
| 1975 | 2.0 | 600 |
| 1976 | 2.0 | 600 |
| 1977 | 1.5 | 400 |
| 1978 | 1.5 | 400 |
| 1979 | 1.5 | 400 |
| 1980 | 1.5 | 400 |
| 1981 and newer | 1.2 | 220 |

I.B. Maximum Concentration Limits for Light-Duty Vehicles (Includes Light-Duty Trucks) Subject to Idle Short Test(s) During Program Phase In

| Model Year | Percent Carbon Monoxide | Parts/million Hydrocarbon |
|---|---|---|
| 1970 and earlier | 5.5 | 1000 |
| 1971 | 4.5 | 1000 |
| 1972 | 4.5 | 1000 |
| 1973 | 4.5 | 1000 |
| 1974 | 4.5 | 1000 |
| 1975 | 3.5 | 600 |
| 1976 | 3.5 | 600 |
| 1977 | 3.0 | 400 |

| | | |
|---|---|---|
| 1978 | 3.0 | 400 |
| 1979 | 2.0 | 400 |
| 1980 | 1.5 | 400 |
| 1981 | 1.5 | 400 |
| 1982 | 1.5 | 400 |
| 1983 | 1.5 | 400 |
| 1984 | 1.5 | 400 |
| 1985 | 1.5 | 400 |
| 1986 | 1.5 | 400 |
| 1987 | 1.5 | 400 |
| 1988 | 1.5 | 400 |
| 1989 and newer | 1.2 | 220 |

**II. HEAVY-DUTY VEHICLES (1978 AND EARLIER GREATER THAN 6000 LBS. GVWR) SUBJECT TO IDLE SHORT TEST(S)**

I.A. Maximum Concentration Limits at Program Maturity

| Model Year | Percent Carbon Monoxide | Parts/million Hydrocarbon |
|---|---|---|
| 1967 and earlier | 7.0 | 1500 |
| 1968 | 6.5 | 1200 |
| 1969 | 6.5 | 1200 |
| 1970 | 5.5 | 1000 |
| 1971 | 5.5 | 1000 |
| 1972 | 5.5 | 1000 |
| 1973 | 5.5 | 1000 |
| 1974 | 5.5 | 1000 |
| 1975 | 5.5 | 1000 |
| 1976 | 5.5 | 1000 |
| 1977 | 5.5 | 1000 |
| 1978 | 5.5 | 1000 |

Heavy-Duty Vehicles (1979 and Newer Greater Than 8500 lbs. GVWR) Subject to Idle Short Test(s)

19794.0 800 19803.5 800 19813.0 600 19823.0 600 19833.0 600 19843.0 600 1985 3.0600 1986 and newer2.0300 II.B. Maximum Concentration Limits During Program Phase In

| Model Year | Percent Carbon Monoxide | Parts/million Hydrocarbon |
|---|---|---|
| 1967 and earlier | 7.0 | 1500 |
| 1968 | 65 | 1200 |
| 1969 | 6.5 | 1200 |
| 1970 | 6.0 | 1200 |
| 1971 | 6.0 | 1200 |
| 1972 | 6.0 | 1200 |
| 1973 | 6.0 | 1200 |
| 1974 | 6.0 | 1200 |

| | | |
|---|---|---|
| 1975 | 6.0 | 1200 |
| 1976 | 6.0 | 1200 |
| 1977 | 6.0 | 1200 |
| 1978 | 6.0 | 1200 |

Heavy Duty Vehicles(1979 and Greater Newer Greater than 8500 lbs. GVWR)Subject To Idle Short Test(s).

19795.01000 19804.01000 19813.5800 19823.5800 19833.5 800 19843.5800 19853.5800 1986 and newer3.0300 III. TRANSIENT TEST MASS EMISSIONS LIMITS IN GRAMS/MILE (GPM) -

III.A. Light-duty vehicles (excluding light-duty trucks)

III.A.1. The following emissions standards shall apply to those tests performed on and after January 1,1999.

| MODEL YEAR | HC | CO | NOx |
|---|---|---|---|
| 1982 | 4 | 45 | 8 |
| 1983 | 4 | 30 | 8 |
| 1984 | 4 | 30 | 8 |
| 1985 | 4 | 20 | 8 |
| 1986 | 3 | 20 | 6 |
| 1987 | 3 | 20 | 6 |
| 1988 | 3 | 20 | 6 |
| 1989 | 3 | 20 | 6 |
| 1990 | 3 | 20 | 6 |
| 1991 | 2.5 | 20 | 6 |
| 1992 | 2.5 | 20 | 6 |
| 1993 | 2.5 | 20 | 6 |
| 1994 | 2 | 20 | 6 |
| 1995 | 2 | 20 | 4 |
| 1996 | 2 | 20 | 4 |
| 1997 | 2 | 20 | 4 |
| 1998 and newer | 2 | 20 | 4 |

III.A.2. The following emissions standards shall apply to those tests performed on model year 1996 and newer vehicles, on and after January 1, of the dates specified.

| CALENDAR YEAR | HC | CO | NOx |
|---|---|---|---|
| 2002 | 1.2 | 20 | 3.0 |
| 2003 | 1.2 | 20 | 3.0 |

III.B. Light-Duty Trucks (equal to or less than 8,500 lbs. G.V.W.R.)

III.B.1. The following emissions standards shall apply to those tests performed on and after - January 1,1999.

| MODEL YEAR | HC | CO | NOx |
|---|---|---|---|
| 1982 | 8 | 65 | 12 |

| | | | |
|---|---|---|---|
| 1983 | 6 | 65 | 12 |
| 1984 | 6 | 55 | 12 |
| 1985 | 6 | 45 | 12 |
| 1986 | 6 | 40 | 9 |
| 1987 | 4 | 30 | 9 |
| 1988 | 4 | 25 | 9 |
| 1989 | 4 | 25 | 9 |
| 1990 | 4 | 25 | 9 |
| 1991 | 4 | 25 | 9 |
| 1992 | 4 | 25 | 9 |
| 1993 | 4 | 25 | 9 |
| 1994 | 4 | 20 | 9 |
| 1995 | 4 | 20 | 9 |
| 1996 | 4 | 20 | 9 |
| 1997 | 4 | 20 | 9 |
| 1998 and newer | 4 | 20 | 9 |

III.B.2. The following emissions standards shall apply to those tests performed or 1998 and newer vehicles on and after January 1, 2015.

| MODEL YEAR | HC | CO | $NO_X$ |
|---|---|---|---|
| 1998 AND NEWER | 4 | 20 | 4 |

III.C. Repealed.

**IV. EVAPORATIVE EMISSIONS CONTROL STANDARDS**

System Integrity - A gas cap integrity check to assess the degree of leakage between the fuel filler neck sealing surface and the gasoline cap sealing surface shall be performed on all model year 1975 and newer vehicles.

IV.A. Pressure decay of the gasoline cap to filler neck sealing surfaces shall not exceed six (6) inches of water over a ten (10) second period, or

IV.B. The gasoline cap flow rate shall be compared to an orifice with a National Institute of Standards and Technology (NIST) traceable flow rate which will result in a pass/fail flow rate threshold of 60 cc/minute of air at 30 inches of water (column).

**V. VEHICLES SHALL NOT EXHIBIT ANY CONTINUOUS GRAY, BLUE, BLUE-BLACK, OR BLACK SMOKE OF GREATER THAN 5% OPACITY FROM THE ENGINE CRANKCASE AND/OR TAILPIPE(S) DURING ANY ENGINE OPERATING CONDITIONS OF APPLICABLE INSPECTION PROCEDURES.**

**VI. CLEAN SCREEN PROGRAM MAXIMUM ALLOWABLE EMISSIONS LIMITS**

VI.A. In order to obtain a Certificate of Emissions Control through the Clean Screen Program, vehicles must not exceed maximum emissions concentrations of 0.50 percent carbon monoxide (CO) and 200 parts per million hydrocarbon (HC) as reflected in remote sensing emissions readings.

VI.B. Vehicle owners who participate in the Clean Screen Program shall not be subject to the provisions

of this Part F other than this section VI.

**PART G Statements of Basis, Specific Statutory Authority and Purpose**

**I. AMENDMENTS TO PART A - E, ADOPTED MARCH 21,1996**

The amendments to Regulation No. 11 were adopted by the Air Quality Control Commission (Commission) of the State of Colorado. This Statement of Basis, Specific Statutory Authority and Purpose is required by Sections 24-4-103(4), C.R.S. The specific statutory authority for these changes are Sections 42-4-301 through 42-4-316, C.R.S. (1995 Supplement).

The revisions to Regulation No. 11 address the effects of recodifying Title 42 of Colorado's Revised Statutes. This regulatory action is necessary to correct statutory references within the regulation in order to be consistent with the renumbered statute. The only other change to the rule is to clarify that "licensed emissions inspectors" are eligible to perform an emissions inspection pursuant to Part C, section I.A. The previous rule referred only to "authorized emissions inspectors" . The purpose of this change is to avoid confusion between emissions inspectors authorized to perform an inspection at an enhanced inspection center and emissions inspectors licensed to do so at an inspection-only facility, fleet inspection station, or motor vehicle dealer test facility. This rule amendment does not change the rights or obligations of any person because the term "authorized emissions inspector" has been applied to include "licensed emissions inspectors" for purposes of Part C section I. A. The specific statutory authority for this rule amendment is set out at Section 42-4-304 (7), C.R.S.

For the reasons noted, the Commission has adopted amendments to Regulation No. 11, Parts A-E. These rule revisions are administrative in nature; do not apply to stationary sources; and will have no regulatory impact on any person, facility or activity. Furthermore, the Commission has no discretion not to adopt the changes to the numbering scheme for the statutory provisions, and these revisions will have no significant fiscal impact. These revisions are not more stringent than the relevant federal requirements.

**II. AMENDMENTS TO PARTS A, B, C, F, G, AND APPENDICES A AND B, ADOPTED JULY 17,1997**

The amendments to Regulation No. 11 were adopted by the Air Quality Control Commission (Commission) of the State of Colorado. This Statement of Basis, Specific Statutory Authority and Purpose is required by Sections 24-4-103(4), C.R.S. The specific statutory authority for these changes is Sections 42-4-301 through 42-4-316, C.R.S. (1995 Supplement).

1. Changes to Part A(I) (C) (9) and (11) address statutory amendments to Section 42-4-309 (6) enacted by the 1996 session of the General Assembly which make provision for an inspection voucher system for retail sale of used motor vehicles into the enhanced emissions inspection program area by licensed dealers. The rule revisions ensure that such dealers are not required to have the vehicle inspected prior to the sale provided they comply with the requirements of Section 42-4-309 (6). Further more, the revisions allow sellers to have a vehicle inspected up to one-hundred twenty days prior to the sale. The specific authority for these changes is set out in Sections 42-4-309 (6) and 42-4-306 (7). This provision is necessary to implement state law, but is not required by federal law. The rule specifically provides that the provisions of 42-4-309 (6) are not federally enforceable, and are not included in the SIP. The Department of Revenue, may however, enforce such requirements, subject to the adoption of any regulations that may be necessary. Such administrative enforcement is necessary to ensure compliance with the statutory requirements. The revisions to Regulation No. 11, Part A(I)(C)(13) make it clear that a vehicle will fail the inspection for purposes of 42-4-309 (6) if the vehicle has any defect that makes it impractical or unsafe to test the vehicle.

2. The revisions to Part A(I)(B) clarify motorist compliance requirements For those persons that live in the basic program area yet commute into and have complied with enhanced program requirements. The specific statutory authority for these changes is set out in Sections 42-4-306 (7) and 42-4-

310 (1) (c) (V). This provision is consistent with, and does not exceed, federal requirements.

3. The revisions to Part C (II)(G)(4) make it clear that vehicles with excessively long or short wheelbases, and specially-designed vehicles equipped with hand controls or similar apparatus, are exempt from testing on the I/M 240 dynamometer. The I/M 240 dynamometer system is not designed to handle such vehicles, and the population of such vehicles is so small that this exemption will have no effect on emissions reductions. This provision is consistent with, and does not exceed, federal requirements. The specific statutory authority for this exemption is set out in Section 42-4-306 (6) (d).

4. The revisions to Part C (III) (D) eliminate the previous requirement to repair or replace the catalytic converter and exhaust gas oxygen sensor if the fuel inlet restrictor has become enlarged. Leaded fuels, which damaged these components, have not been available for several years and this rule is no longer necessary. This provision is consistent with, and does not exceed, federal requirements. The specific statutory authority for this exemption is set out at Section 42-4-306 (6) (a).

5. The revisions to Part C (XI) allow inspection stations to use vehicle identification numbers (VINs) issued by kit car manufacturers and by other states. The rule previously required inspection stations to use a VIN assigned by Colorado for kit cars, custom cars and home-built vehicles. Under the previous rule, such specialized vehicles were often required to comply with inspection criteria applicable to later model vehicles. As a result the inspection criteria were unreasonably stringent. This change will ensure that vehicles are inspected pursuant to the appropriate procedure, This provision is consistent with, and does not exceed, federal requirements. The specific statutory authority for this provision is set out at Section 42-4-306 (6).

6. The revisions to Parts C (IV) and F (IV) provide a pressure integrity or leak check for gas caps in order to reduce emissions of volatile organic compounds, an ozone precursor. The gas cap pressure check requirements is based on established demonstrated methodologies, and will provide an estimated 40% reduction in VOC, an ozone precursor, to escape into the atmosphere. Such evidence supports the finding that the rule will result in a demonstrable reduction in air pollution. Because the Denver area is in the inspection and maintenance program due to carbon monoxide, rather than ozone problems, federal law does not require such a pressure check. The state did not take credit for such a pressure check in the maintenance plan for ozone, and associated redesignation request, recently adopted by the AQCC. Therefore, this provision is not required by federal law, and will not be incorporated into the State implementation Plan. An evaporative emissions inspection procedure is required pursuant to Sections 42-4-310 (2) (a) and 42-4-306 (6) (a), C.R.S. for those vehicles inspected in the metro Denver enhanced program area.

7. The revisions to Part B (IV)(B&C), (VI)(C&D) and Appendix B propose standards and specifications consistent with EPA and recognized industry standards for the manufacturer and “naming” of precision calibration gases for use in test analyzer systems. Consistent protocol reduces the burden to the gas manufacturer, those regulated parties which are end users of the calibration gases, and improves overall quality control. Additionally, revisions to Appendix B address specific program administrative needs such as the bar code tracking system necessary for tracking certified test analyzer system gases which have been placed into service. The revisions to Appendix B are consistent with guidance documents issued by EPA. Federal law requires span gases to be accurate within a tolerance of 2%, but federal law does not specifically require the state to establish requirements for manufacturers. Therefore, the requirements set out in Appendix B shall not be included in the SIP, and shall not be federally enforceable. The specific statutory authority for this action is Section 42-4-306 (3)(a)(I).

8. The revisions to Appendix A, attachment III establish equipment design and performance specifications for a “Motor Vehicle Dealer Transient Mode Test Analyzer System (I/G 240)” to be used at Motor Vehicle Dealer Test Facilities (MVDTFs). Equipment that meets these specifications will allow MVDTFs to conduct emissions inspections on their used vehicle inventory

prior to its retail sale. This provision provides increased convenience and reduced costs for affected automobile dealers that currently utilize the contractor operated I/M 240 system in the enhanced program area. Use of this system is not mandated. Federal law does not require specifications for an I/G 240, and the state did not take credit for inspections conducted at the time of sale or transfer of used vehicles sold by motor vehicle dealers. Therefore, the specifications applicable to MVDTFs and the I/G 240 are not included it the SIP. The specific statutory authority for this revision is Sections 42-4-304 (19) and 42-4-306 (3)(a)(I)(A-C).

9. Revisions to Part A(I)(9) delete the present exemption that vehicles sold as “tow-away” by licensed dealers are not required to comply with applicable emissions inspection requirements at the time of sale. The proposal would eliminate present confusion within the regulated community. Part A (I) (9) is now consistent with Section 42-4-309(3)(a). The Commission is not required to create a specific exemption for tow-away vehicles and therefore has the authority to remove the existing exemption. Additional statutory authority is set out at Sections 42-4-306 (1) and 42-4-309 (3)(A).

   The Department of Revenue is the state agency charged with the regulation of motor vehicle dealers, and for the titling and registration of motor vehicles. The tow-away exemption has hampered the Department of Revenue's enforcement actions. Therefore, the Commission is repealing this exemption and deferring this issue to the Department of Revenue. The Department of Revenue should handle this issue through rule-making or otherwise, as appropriate.

10. Revisions to Part A (V) amends the notice to interested parties that materials incorporated into the rule by reference may be examined at any state publications depository library, as required by Section42-4-103 (12.5)(d). The revision expands the text of the existing notice of availability to be consistent with. prescriptive state requirements.

    For the reason noted, the Commission has adopted amendments to Regulation No.11, Parts A, B, C, F, G and Appendices A and B. Revisions implement and/or clarify statutory provisions for the vehicle emissions inspection program pursuant to Sections 42-4-301 through 42-4-316, C.R.S. Rule revisions amend existing inspection procedures consistent with State Implementation Plan commitments.

**III. NOVEMBER 19,1998, REVISIONS TO PART C (VIII) AND PART F (III)**

Basis and Purpose

The November 19, 1998 revisions to regulations Part C (VIII) (b.4) (b.5) and (c.-g.) reinstate, with some minor clarifications, text addressing compliance waivers and related inspection provisions regarding specific circumstances involving certain participating motorists and the repair of vehicles that had failed one or more emissions inspections. This text was inadvertently omitted during the last publication of the regulation, August 1997. The omitted text was initially adopted by the Commission immediately prior to implementing the improved basic program and enhanced inspection and maintenance program January 1995, pursuant to Sections 42-4-301 through 42-4-316, C.R.S. (1998). Reinstating this text results in the regulation being consistent with state statute and the federal program. The November 19,1998 revisions to regulations Part F (III) reconcile the emissions limits used by enhanced inspection centers for motor vehicle emissions inspections with the emissions limits that were used for purposes of demonstrating attainment of the National Ambient Air Quality Standards (NAAQS) for carbon monoxide (CO) and for particulate matter less than ten microns in diameter (PM10). The rule change only applies to the enhanced emissions program and only affects the standards used for testing 1982 and newer vehicles.

The emissions limits adopted by the Commission are more stringent than the emissions limits that were being implemented prior to the hearing, but are less stringent than the emissions limits that were scheduled to take effect on January 1,1999 under the previous version of Regulation No. 11.

The emissions limits adopted by the Commission must go into effect by the end of December 1998 in

order to comply with the minimum federal requirement to show attainment of the NAAQS for CO by December 31,2000.

The emissions limits contained in the previous rule for 1999 and beyond were more stringent than necessary to comply with federal law and were so stringent that many vehicles would not be able to comply with the standards even when repaired. Such emissions limits were based on EPA guidance issued in 1993. Experience with the program since then has demonstrated that such standards are unreasonable.

Federal Requirements

There are several federal requirements that are relevant to the emissions limits used in the AIR Program. 40 CFR Part 51 establishes specific emissions limits for the AIR Program. In addition, the AIR Program was used to demonstrate attainment of the NAAQS for CO and PM10. Therefore, the emissions limits must be included as enforceable control measures in the State Implementation Plan.

For purposes of CO, 40 CFR section 51.351 requires the AIR Program to achieve at least as much reduction in fleet emissions, measured in grams per mile, as the model federal program. The modeling results that were used to demonstrate compliance with the requirements of 40 CFR Part 51 were also used to demonstrate attainment of the NAAQS for CO in the Denver CO SIP. The emissions limits for CO and hydrocarbons implement the assumptions that were made in the modeling to show compliance with 40 CFR 51.351 and to show attainment of the CO NAAQS. The emissions limits for hydrocarbons are a necessary component of an effective CO control program and, therefore, are being included in the State Implementation Plan.

The emissions limits for $NO_X$ for the years 1999 through 2014 established in the rule are necessary to achieve the $NO_X$ reductions that were assumed for the AIR Program in the Denver PM10 SIP. Thus, such emissions limits are necessary to implement the control measures contained in the Denver PM10 SIP as required by federal law.

For the foregoing reasons, the Commission concludes that the emissions limits in Regulation No. 11 for the years 1999 through 2014 are necessary to comply with federal law and do not otherwise exceed the minimum federal requirements. However, the rule revision also includes an emissions limit for $NO_X$ for the year 2015 and beyond that is more stringent than the minimum federal requirements. Such more stringent $NO_X$ limit is necessary beginning in the year 2015 in order for the Denver Regional Council of Governments (DRCOG) to demonstrate that the transportation network for the Denver metropolitan area will remain below the emissions budget for NOX in the State Implementation Plan. Pursuant to federal law, such a control measure must be adopted by the Commission before DRCOG makes its conformity determination. 40 CFR 93.122(a)(3)(l). However, federal law does not require the such more stringent emissions limit for $NO_X$ to be included in the State Implementation Plan. Therefore, the emissions limit for $NO_X$ established in Part F, sections III.A.2 and III.B.2 shall not be included in the State Implementation Plan.

Statutory Authority

The specific statutory authority for the adoption of emissions limits for carbon monoxide, hydrocarbons and oxides of nitrogen is set out at Section 42-4-306(6), C.R.S. (1998).

Effective date of rule changes

Pursuant to Section 24-4-103(5), C.R.S. (1998), the standards or cut-points established by the Commission on November 19,1998 shall take effect on December 30, 1998; provided the rule revisions are published in the Code of Colorado Regulations on December 10, 1998. Such an effective date is consistent with the relevant SIP demonstrations. For purposes of Section 42-4-306(6)(b)(ll), C.R.S. (1998), the standards established by this rule revision were established on November 19,1998 even

though such standards shall not become effective until December 30,1998.

Findings pursuant to § 25-7-110.8. C.R.S. (1998).

The revisions to Regulation No. 11 are based on reasonably available, validated, reviewed and sound scientific methodologies. The Commission has considered all scientific and other information made available by interested parties.

Evidence in the record supports the finding that the revised emissions limits will result in a demonstrable reduction in air pollution when compared to the emissions limits that were in effect prior to the rule change.

The rule adopted by the Commission is the most cost-effective alternative, and will maximize the air quality benefits of the regulation in the most cost-effective manner.

**IV. FEBRUARY 19,1999, REVISIONS TO PARTS A, B, C, D, AND F**

Basis and Purpose

The February 19,1999 revisions implement Sections 42-4-304 through 42-4-307 and 42-4-310, C.R.S. as amended, pursuant to S.B. 98-182. Additionally, the revisions codify the provisions of Sections 42-4-304 and 42-4-310, C.R.S. as amended, pursuant to S.B. 98-182.

Explanation of the Provisions

The revisions implement a “Clean Screen Program” as an operating element of Colorado's AIR Program as established in Sections 42-4-301 through 42-4-316, C.R.S. The Clean Screen Program is designed and intended to improve participating motorist convenience and reduce costs when complying with a periodic inspection requirement. Screening clean vehicles out of the vehicle population subject to inspection requirements reduces the burden of compliance on vehicle owners. One program premise is that these vehicles would have passed a traditional inspection and that air quality would not necessarily benefit from using traditional inspection procedures on these vehicles. Clean screened vehicles would be exempt from complying with what would normally be mandatory inspection, for one inspection cycle.

Participation by owners of vehicles registered in the program areas specified, i.e., Larimer County and metro Greeley, Weld County as well as by owners of vehicles registered else where but required to obtain a certification of emissions compliance by Section 42-4-310 (l)(c)(I), C.R.S., is voluntary. Provisions within the enabling legislation allow for participation by other program areas or for other areas of the state based upon a request by respective lead air quality planning agencies, and approval by the Commission.

As proposed for implementation in the Larimer County and Weld County program areas, Clean screening is an appropriate application of remote emissions sensing technology. Based on the Greeley Pilot Study conducted by the Division, implementing this technology as an alternate inspection procedure brings with it an estimated maximum 4-7% loss in emissions reduction compared to traditional inspection procedures. The Environmental Protection Agency's modeling projects a 1% loss. The Commission concludes that this loss of emissions reductions will have no negative impact on compliance with the National Ambient Air Quality Standards for the areas included.

Reducing the number of vehicles seeking an inspection each cycle will reduce business for licensed inspection providers serving these program areas.

The Division is committed to continuously evaluating the performance of the program especially as it pertains to the specific emissions thresholds used in the program, impacts on air quality, and may request the Commission to consider revisions to elements of the program. Additionally, the Division has committed to evaluating the feasibility of low emission(s) profiling as a supplementary inspection criteria

to a Clean Screen Program.

Statutory Authority

Sections 42-4-304 through 42-4-307, and Section 42-4-310, C.R.S., as amended, authorize adoption of a Clean Screen Program.

Federal Requirements

There are no specific federal requirements requiring a Clean Screen Program. This program is not a federal mandate. The United States Environmental Protection Agency has published general guidance which is reflected in the revised regulations. A revision of the SIP for the applicable program areas is necessary to reflect the potential emissions reduction impact associated with Clean Screen Program procedures.

Explanation of Additional Revisions to Regulation for February 19,1999.

The revisions to the regulation also implement the provisions of Sections 42-4-304 and 42-4-310, C.R.S., as amended, pursuant to SB 98-046 as it pertains to the responsibility of compliance with emissions inspection requirements for vehicles in the process of being sold. The provisions require the seller to obtain an emissions inspection when the vehicle is operable and can be tested. Where the vehicle is deemed inoperable or otherwise cannot be tested, the seller must provide written notice to the purchaser prior to completion of the sale on specific forms prepared by the Department of Revenue.

Statutory Authority

The specific statutory authority for the provisions discussed above is set out at Sections 42-4-304 and 42-4-310, C.R.S. as amended. The Department of Revenue adopted and implemented regulations to address these provisions. Regulation 11 is now consistent with state statute.

Federal Requirements

There are no federal requirements as it pertains to these provisions.

Effective Date of Rule Changes

The effective date for the revisions to Regulation 11 shall be April 30,1999.

**V. AMENDMENTS TO PARTS A, C AND F (III), ADOPTED JANUARY 10, 2000**

Basis and Purpose

Regulation No. 11 requires periodic emissions tests for vehicles registered or operating within the program area, which covers most of the Front Range. The purpose of the program is to reduce the amount of carbon monoxide, oxides of nitrogen, and hydrocarbons emitted by automobiles. The purpose of the January 2000 revisions to Regulation No. 11 is to make the program more cost-effective and more convenient for motorists, and to do so in a manner that protects air quality.

This rule revision makes two changes to the motor vehicle emissions inspection program. First, it extends the clean screen program to the Denver metropolitan area. The clean screen program uses remote sensing technology to identify vehicles that do not need to be tested at an emissions inspection station. Beginning in the year 2002, the revised rule will allow a motorist that passes the requisite remote sensing test to obtain a certification of emissions compliance through the mail without taking the vehicle to an inspection station for a test.

Second, the rule-revisions amend the emissions standards for 1996 and later motor vehicles, beginning in the year 2002. The revisions make the standards consistent with the air pollution control technology on new vehicles.

Federal Requirements

The revisions to Regulation No. 11 were developed in conjunction with the redesignation of the Denver metropolitan area as an attainment area for carbon monoxide. Section 175 (a) of the federal Clean Air Act requires the State to demonstrate that the region will remain within the national ambient air quality standard (NAAQS) for carbon monoxide for ten years after EPA takes action on the maintenance plan. EPA may not take action on the maintenance plan until 2002. Thus, federal law requires the maintenance plan to show compliance with the NAAQS for carbon monoxide through the year 2013.

Air quality analyses performed for the maintenance plan indicate that the region will remain within the NAAQS for carbon monoxide through the year 2010, even with the clean screen program. The tools currently available for predicting air quality in the future suggest, however, that the clean screen program may be inconsistent with maintenance of the NAAQS for carbon monoxide after 2010. The rule revisions provide for the expiration of the clean screen program in the year 2010 in order to demonstrate maintenance of the NAAQS through 2013.

The rule revisions codify the emissions standards that were used to perform the computer modeling to demonstrate maintenance of the NAAQS. In performing the requisite computer modeling, the Air Pollution Control Division (APCD) used emissions standards that are more stringent than appeared in Regulation No. 11 prior to these amendments. The APCD used the more stringent standards in order to maximize the air quality benefits of the program for purposes of the computer model. Although the revisions make more stringent the emissions standards in the rule, the changes do not necessarily make the program as a whole more stringent. This is because, as a practical matter, more stringent standards will automatically apply under pre-existing state and federal law. The federal rules require vehicle manufacturers to equip all 1996 and later light-duty vehicles with on-board diagnostic systems that will cause vehicles with emissions in excess of the revised standards to display fault codes (40 CFR section 86.094-17). Regulation No. 11 already provides that a vehicle will fail the emissions test if the on-board diagnostic system displays such a fault code (Regulation No. 11, Part C, Section III.C). The result is that the federal standards for the on-board diagnostic systems (which are more stringent than even the revised standards) already apply as a practical matter. The rule change is necessary to allow the APCD to take credit for more stringent standards when performing the computer modeling exercise. The revision merely make the standards consistent with improved technology that vehicle manufacturers are using to meet the on-board diagnostic requirements and to meet the Tier-1 standards mandated by federal law. The revised standards do not exceed the requirements of federal law.

The air quality impacts of the revisions to Regulation No. 11 were analyzed using the computer models approved by EPA, as is required by federal rules. Regulation No. 11, as revised, is necessary to comply with the requirements of the federal act and is not more stringent than the requirements of the federal act.

Statutory Authority

Specific statutory authority for the extension of the clean screen program to the Denver area is provided in section 42-4-306(23), C.R.S. (1999). Specific statutory authority to establish emissions standards is provided in section 42-4-306(6)(a), C.R.S. (1999).

Findings pursuant to section 25-7-110.8

The primary intent of the January 2000 changes to Regulation No. 11 is to make the motor vehicle emissions inspection program more convenient and less costly, rather than achieving further reductions in emissions of air pollution. In addition, the rules establish more stringent emissions standards for automobiles in order to make the standards consistent with technology mandated by federal law.

The revisions are based on the computer model currently approved by the EPA. The computer model used to develop the revised rule overstates the carbon monoxide problem the Denver area will face in the future. The EPA is currently updating and improving the computer model but the revised computer model has not been approved by EPA and may not be used for federal regulatory purposes. In spite of the problems with the computer model used to develop this regulation, the regulation is based on the most reasonably available, validated, reviewed and sound scientific methodologies currently available under federal law. All methodologies and information made available by interested parties have been considered.

The alternative chosen by the Commission provides the regulated community flexibility and achieves the necessary reduction in air pollution. The evidence is insufficient for the Commission to determine that the alternative chosen by the Commission is the most cost-effective alternative. The cost analysis developed by the Division indicates that it may be more cost-effective to eliminate the oxygenated fuels program instead of implementing a clean-screen program, but there is considerable uncertainty in that cost estimate. The impact of oxygenates on gasoline prices varies from year to year depending on the cost of ethanol and gasoline. Thus, reducing the oxygen content of gasoline does not ensure lower consumer gasoline prices. The Commission chose the alternative proposed by the Regional Air Quality Council (RAQC) for several reasons. First the RAQC's proposal is a balanced proposal that was developed through an inclusive stakeholder process. Second, it will establish a remote-sensing network, which is a necessary first step to establish a cost-effective high-emitter program in the future. Finally, the selection of a different option could delay the redesignation of the Denver area and would delay any cost-savings associated with such alternative.

**VI. AMENDMENTS TO PARTS C AND D ADOPTED NOVEMBER 16, 2000**

Basis and Purpose

This rule revision makes two changes to the motor vehicle emissions inspection program. First, the change to Part C, section XII.E.2 extends the time period for taking valid emissions readings for purposes of the clean screen program. This section previously required a reading within 90 days of the registration renewal date for the relevant motor vehicle. Since it often takes 90 days just to correlate the data, make the necessary communications and receive payment for the motorist, this time period was too restrictive and made the clean screen program impractical. The time period was extended by a minimum of 30 days to allow more time for emissions readings.

Second, the provision on licensing requirements for clean screen inspectors in Section IX.B.7 erroneously required such inspectors to demonstrate proficiency with the criteria in Section II.A.2 (qualifications for emissions mechanics and emissions inspectors) rather than Section V (qualifications for dean screen inspectors). The rule revision corrects this citation error.

Federal Requirements

The federal act and EPA regulations do not mention clean screen programs. *See,* 40 CFR Part 51, Subpart S. EPA has, however, developed a draft guidance document that authorizes the use of dean screen programs to exempt certain vehicles from the federally-required automobile inspection program. EPA document 420-P-98-008 (May 1998). The draft guidance document requires two remote-sensing readings, but does not require the readings to be any more recent than twelve months prior to the vehicle's regularly-scheduled emissions test.

The clean screen program is voluntary and is designed to reduce the burden of the federally based automobile inspection program described at 40 CFR Part 51, subpart S. Overall, the clean screen program results in an automobile inspection program that is less stringent than the program described in the federal regulations. Thus, the amendments will result in a motor vehicle inspection program that is less stringent than the program described in the federal regulations, but that requires more recent test results than is required by the draft federal guidance. Because EPA does not expressly require such a cutoff date, the revised rule will not be part of the federally-enforceable SIP.

Although not expressly required by draft federal guidance, the requirement for a recent emission reading is necessary and reasonable to ensure that the emission test is representative of vehicle emissions near the time of registration. Motor vehicle emissions deteriorate over time. It follows that emission readings should be considered valid for a limited period of time. The General Assembly intended for 1982 and newer vehicles to be inspected every twenty-four months. Section 42-4-310(1 )(b)(ll)(C), C.R.S. A vehicle that passes a clean screen test based on a reading taken 120 days prior to the registration renewal date can go twenty-eight months without inspection (or even twenty-nine months if the motorist takes full advantage of the one month grace-period allowed by the Department of Revenue following the registration renewal date). The requirement for an emissions reading within 120 days of the registration renewal date strikes a reasonable balance between the requirement to implement a clean screen program and the legislative intent for emissions tests every two years.

The federal requirements for the licensing or certification of inspectors are set out at 40 CFR 51.367. The criteria established in Regulation No. 11, Part D, Section V are not more stringent than the federal requirements.

Statutory Authority

Specific statutory for the authority to promulgate regulations governing the operation of the clean screen program is set out at 42-4-306(23), C.R.S.

Findings Pursuant to 25-7-110.8. C.R.S.

The primary intent of the November 2000 changes to Regulation No. 11 is not to achieve further reductions in emissions of air pollution, but rather to make more practical the administration of the clean screen program. Thus, the rule revision is administrative in nature.

The expanded time period allows additional time for taking emission measurements, analyzing the data, and communicating with motorist and the Clerk and Recorder. The revision to the time period does not change the standards or technology used in the program. The revision is consistent with all relevant, reasonably available, validated, reviewed, and sound scientific methodologies. All validated, reviewed, and sound scientific methodologies and information made available by interested parties has been considered.

The rule revision makes the dean screen program more cost-effective, provides the contractor and motorists with greater flexibility, will achieve the necessary reduction in air pollution, and will maximize the air quality benefits of the automobile inspection program in the most cost-effective manner.

**VII. AMENDMENTS ADOPTED DECEMBER 20, 2001.**

Basis and Purpose

The December 2001 revisions to Regulation No 11 do three things: First, the rule revisions expand the clean screen program to include the enhanced emissions program area. However, the Commission did not, at this time, establish an implementation schedule pursuant to Section 42-3-134, C.R.S. This rule change is necessary to establish the clean screen authority pursuant to Section 42-4-307.5(1), C.R.S. The creation of the clean screen authority is necessary so that the Colorado Department of Revenue may receive and expend funds pursuant to Sections 42-4-307(10.5)(a) and section 13 of House Bill 2001 -1402 (“HB1402” ). Thus, this portion of the rule change has no regulatory effect other than :he creation of the clean screen enterprise. The Commission intends to hold a subsequent rulemaking hearing to establish an implementation schedule.

Second, the rule change excludes the El Paso county portion of the basic emissions program area from the clean screen program pursuant to Section 42-4-306(23)(a), C.R.S.

Third, the revisions conform Regulation No. 11 to the provisions of HB 1402 which repealed the Verification of Emissions Test requirements.

Federal Requirements

Although federal rules establish minimum performance requirements for the basic and enhanced emissions programs, nothing in the federal rules bear directly on the rule changes that were the subject of the December 2001 rulemaking hearing. The revised rule does not exceed the minimum requirements of federal law.

Statutory Authority

The specific statutory authority to expand the clean screen program to enhanced emissions program area is set out at 42-4-306(23)(b), C.R.S. The specific statutory authority to exclude the El Paso county portion of the basic emissions program area from the clean screen program is set out at 42-4-306(23)(a), C.R.S. The statutory authority to conform the Regulation to the applicable statutory provision is set out at 42-4-306(1), C.R.S.

Findings Pursuant to 25-7-110.8. C.R.S.

The requirement for findings set out in section 25-7-110.8, C.R.S. does not apply to this rulemaking hearing. The creation of the clean screen authority is merely an administrative change; it is not intended to reduce air pollution. Similarly, the exclusion of El Paso County from the clean screen program is exempt from the requirements of 25-7-110.8 because it makes no change to the program applicable in that area because El Paso County was already exempt from the clean screen program. This rule change merely formalizes the area's status in the wake of HB 1402. Finally, the Commission has no discretion concerning the repeal of the provisions related to the verification of emissions tests. For these reasons, 25-7-110.8 does not apply to this matter.

**VIII. AMENDMENTS TO PART A ADOPTED JULY 18, 2002**

Basis and Purpose

This rulemaking action removes the Fort Collins area component of the Automobile Inspection and Maintenance Program (“AIR Program” ) from the State Implementation Plan (SIP), but does not make any change in the state laws implementing the program. This means that the AIR Program will remain in full force and effect under state laws, but it will not be federally-enforceable after January 1, 2004. The continuation of the AIR Program as a state-only program will afford the Division and the City of Fort Collins an opportunity to work together to identify feasible options to replace the AIR Program in the Fort Collins area.

The maintenance plan adopted by the Commission in conjunction with these rule changes includes a commitment to begin implementing the AIR Program in the Fort Collins area in the year 2026. Such a commitment is necessary to authorize state and local transportation planning agencies to take emissions reduction credit for such a program when such agencies make transportation conformity determinations 40 CFR 93.122(a)(iii). The Commission intends to reevaluate this commitment when it revises the maintenance plan, as it is required to do within eight years pursuant to as required by 42 USC 750 a (b), and may, in compliance with all applicable state and federal laws, revise the commitment as necessary and appropriate.

Federal Requirements

After January 1,2004, the basic AIR Program will no longer be necessary to maintain the National Ambient Air Quality Standards for carbon monoxide in the Fort Collins area through the year 2015. Therefore, the program is no longer a federal requirement for the Fort Collins area. The Commission is

removing the program from the State Implementation Plan, but is not repealing the program. The basic AIR Program will continue to apply in the Fort Collins area. Thus, the provisions of Regulation No. 11 applicable to motorists registered in the Fort Collins area are not required by federal law and are more stringent than the minimum federal requirements.

## IX. AMENDMENTS TO PARTS A AND C ADOPTED AUGUST 15, 2002

Basis and Purpose

The primary purpose of this rulemaking action is to switch Larimer and Weld counties to a pay-upon-registration system for the Clean Screen Program. The purpose of the Clean Screen Program is to make the Automobile Inspection and Readjustment Program ("the AIR program" ) more convenient, although not necessarily less expensive. The intent behind the pay-upon-registration system is to make it easier for motorists to pay for dean screen tests. Motorists were previously required to make a separate payment to the contractor by mail before a dean screen test could be used to register a motor vehicle. With the change adopted by the Commission, motorists will be able to pay for dean screens tests at the time of registration. This change should make the Clean Screen Program, and therefore the AIR Program, more convenient for motorists. This rule change is intended merely to give motorists an option.

Clean screen motorists will have the choice of paying for the clean screen test and using it to register the vehicle, or having the vehicle tested at a conventional inspection and readjustment station and paying for such test at the testing station.

The rule amendments include a change to the timing requirements for remote sensing readings to make the Clean Screen Program more flexible. As amended, the regulation requires two valid remote sensing readings within a twelve-month period in order to clean screen a vehicle. The regulation previously required the most recent reading to be within 120 days of the registration renewal date. The 120-day requirement exceeded the minimum federal requirement. The rule has been revised rule to reflect EPA guidance and to maximize the use of the Clean Screen Program. The contract provides for adequate quality assurance by requiring the contractor to return to the same remote sensing locations on a frequent basis. Such rotation of the remote sensing units should minimize the number of vehicles that are dean screened based solely on readings taken early in the twelve-month period.

In addition, the rule changes include several minor, housekeeping changes such as:

> The elimination of a requirement for the agencies to develop the equivalent of a windshield sticker for clean screened vehicles. Such a rule was inconsistent with the change in statute eliminating the windshield sticker requirements.
>
> The elimination of a provision requiring annual inspections for government vehicles. Such a rule was inconsistent with a change in statute establishing biennial inspections for such vehicles.
>
> The repeal of provisions establishing a method to mail payments to the contractor.

Federal Requirements

There are no federal requirements relevant to the payment mechanism for the Clean Screen Program. As indicated above, the purpose of this change is to make the program more convenient and to provide motorists with an option. Although the AIR Program may not be federally required in Larimer or Weld county after January 1, 2004, federal law requires the continued implementation of the AIR program in such areas until removed from the SIP through the SIP revision process. In the meantime, motorists must pay for emissions tests. Therefore such payment requirements do not exceed minimum federal requirements.

For clean screen programs, federal guidelines require two remote sensing readings within twelve months.

The rule change makes the Colorado rule identical to the federal guideline.

For these reasons, this rule change does not exceed minimum federal requirements and is not otherwise more stringent than federal law.

Statutory Authority

The statutory authority to establish the specific dates for county clerks and recorders to begin collecting emissions inspection fees is set out at Section 42-3-134(26.5)(a), C.R.S. The Commission expressed the start date as the month in which motor vehicle registrations come due in order to effectively coordinate the Commission rules with the motorist notification process used by the County Clerks and Recorders.

In addition Section 42-4-306(1) grants the Commission the authority to promulgate such regulations as may be necessary to implement the Automobile Inspection and Readjustment Program, which authority extends to all the relevant rule changes.

Findings Pursuant to 25-7-110.8. C.R.S.

The requirements of 25-7-110.8 do not apply to the August 15,2002 rule revisions because such revisions were not adopted for the purpose of reducing air pollution. Section 25-7-110.8 requires the Commission to make express findings whenever it imposes new regulatory requirements to improve air quality. The changes are administrative in nature and that are designed to implement the Clean Screen Program and the pay-upon-registration program in an efficient and cost-effective manner. Therefore, the requirements of Section 25-7-110.8 do not apply here.

## X. AMENDMENTS TO PARTS A AND C ADOPTED OCTOBER 17, 2002

Basis and Purpose

This rulemaking action implements the Clean Screen Program in the enhanced emissions program area. The purpose of the Clean Screen Program is to make the Automobile Inspection and Readjustment Program (“the AIR program” ) more convenient, although not necessarily less expensive. This rule change is intended merely to give motorists the option of using the Clean Screen Program. Clean screened motorists will have the choice of paying for the clean screen test and using it to register the vehicle, or paying to have the vehicle tested at a conventional inspection and readjustment station and paying for such test at the testing station.

The rule was also changed so that the malfunction indicator light (MIL) and on-board diagnostic (“OBD II” ) fault codes will not be used as the basis for test failures. Data provided by the Division reveals that MIL and OBD II requirements are not cost effective test criteria.

Federal Requirements

There are no relevant federal requirements to the payment mechanism for the Clean Screen Program. As indicated above, the purpose of this change is to make the program more convenient and to provide motorists with an option.

Nothing in federal law requires MIL or OBD tests for pre-1996 vehicles. The rule change eliminates a pre-existing state requirement for such vehicles to pass MIL tests. The rule change also eliminates the requirement for 1996 and newer vehicles to pass MIL and OBD tests. Although federal law requires OBD tests on such newer vehicles registered in certain carbon monoxide and ozone nonattainment areas, such federal requirement no longer applies in Colorado because all carbon monoxide and ozone areas have been redesignated to attainment.

For these reasons, this rule change does not exceed minimum federal requirements and is not otherwise

more stringent than federal law.

Statutory Authority

The statutory authority to establish the specific dates for County Clerks and Recorders to begin collecting emissions inspection fees is set out at Section 42-3-134(26.5)(a), C.R.S. The Commission expressed the start date as the month in which motor vehicle registrations come due in order to effectively coordinate the Commission rules with the motorist notification process used by the County Clerks and Recorders.

The authority to revise the OBD and MIL requirements is set out in Section 42-4-306((i)(a).

Findings Pursuant to 25-7-110.8. C.R.S.

The requirements of 25-7-110.8 do not apply to the October 2002 rule revisions. Section 25-7-110.8 requires the Commission to make express findings only when it imposes new or amended regulatory requirements intended to reduce air pollution. Essentially, the statute requires the Commission to determine that the costs and burdens imposed by the new or more stringent requirements are justified by the air quality benefits. The purpose of the October 2002 rule changes is to reduce the burden of Automobile Inspection and Readjustment Program. Therefore, the requirements of Section 25-7-110.8 do not apply to such revisions.

**AMENDMENTS TO PART C ADOPTED NOVEMBER 21, 2002**

Basis and Purpose

This rule change requires the Division to make annual adjustments to the minimum expenditure required to qualify for a certification of emissions waiver, based on the consumer price index for all urban consumers for the Denver-Boulder metropolitan statistical area as authorized by Section 42-4-310(1)(d)(VI), C.R.S. The rule adopted by the Commission requires the Division to make such annual adjustments through the year 2004. The Commission intends to re-evaluate the waiver amount in 2004. At such time, the Division shall submit to the Comission an analysis of cost and emission reduction benefit, if any, associated with the adjustments to the waiver amount.

In addition, the rule was also modified so that changes adopted by the Commission at their October 17,2002 hearing, concerning malfunction indicator light (MIL) requirements, will be delayed until April 1,2003 to provide an opportunity to complete necessary computer software changes.

Federal Requirements

The federal requirements for an emissions waiver is set out in 40 CFR 51.360(a)(7). The federal rule requires a minimum expenditure of $450, which amount is to be adjusted annually, beginning in 1998, based on the consumer price index. However, the federal requirement applies only in certain carbon monoxide nonattaiinment areas. The federal requirement no longer applies to the Denver area since it has been redesignated as an attainment area for carbon monoxide, provided the waiver rate does not exceed 3% of the failed vehicles. Arguments can be made both ways on the question of whether the rule change exceeds minimum federal requirements. Arguably, it does not because the revised rule is consistent with the intent of the federal law to annually adjust the waiver amount based on the consumer price index.

Statutory Authority

The authority to revise the waiver amount is set out in Section 42-4-310(1 )(d)(VI), C.R.S.

The authority to delay the effective date of the rule change concerning the MIL is set out in Section 24-4-103(5), C.R.S.

Findings Pursuant to 25-7-110.8. C.R.S

The revision of emissions repair waiver limits brings the waiver limits in line with the customer cost index. The rule revision is based on reasonably available, validated, reviewed, and sound scientific methodologies. All validated, reviewed, and sound scientific methodologies and information made available by interested parties has been considered. Evidence in the record supports the finding that the rule shall result in a demonstratable reduction in air pollution. The rule revision is the most cost-effective alternative, provides the regulated community flexibility, and achieves the necessary reduction in air pollution. The revised rule will maximize the air quality benefits of the regulation in the most cost-effective manner.

The requirements of 25-7-110.8 do not apply to the rule revision delaying repeal of the MIL test requirement. Section 25-7-110.8 requires the Commission to make express findings only when it imposes new or amended regulatory requirements intended to reduce air pollution. Essentially, the statute requires the Commission to determine that the costs and burdens imposed by the new or more stringent requirements are justified by the air quality benefits. The rule revision concerning delay of the MIL test requirement make implementation of the Commission revisions of October 17,2002 possible,.and thus reduce the cost and burden of the Automobile Inspection and Readjustment Program. Therefore, the requirements of Section 25-7-110.8 do not apply to such revisions.

**XII. AMENDMENTS ADOPTED DECEMBER 19, 2002**

Basis and Purpose

This rulemaking action removes the Greeley component of the Automobile Inspection and Maintenance Program (“AIR Program” ) from the State Implementation Plan (“SIP” ), effective January 1,2004. The AIR Program would remain a state-only program while the lead air quality planning agency for the Greeley area evaluates options for discontinuing the program altogether or retaining it as a local program. The AIR Program for the Greeley area has been removed from the SIP because it is no longer necessary for the Greeley area to meet the ambient air quality standards.

The maintenance plan adopted by the Commission in conjunction with these rule changes includes a commitment to begin implementing the AIR Program in the Greeley area anew in the year 2026. Such a commitment is necessary to authorize state and local transportation planning agencies to take emissions reduction credit for such a program when such agencies make transportation conformity determinations, 40 CFR 93.122 (a) (iii). The Commission intends to reevaluate this commitment when it revises the maintenance plan, as it is required to do within eight years pursuant to as required by 42 USC § 750 a (b), and may, in compliance with all applicable state and federal laws, revise the commitment as necessary and appropriate. The rule resulting from this rule change exceeds minimum federal requirements because air quality modeling shows that the AIR Program is not necessary to maintain the national ambient air quality standard for carbon monoxide in the Greeley area after 2003.

Specific Statutory Authority

The application of the Basic AIR Program to the Greeley area is prescribed in state statute, Section 42-4-304(20)(a)(V). The Commission has the statutory authority to adopt a comprehensive State Implementation Plan (SIP) and to decide which control measure should be included in such SIP, Section 25-7-105, C.R.S. The Commission is required to exclude from the SIP rules that exceed the minimum requirements of federal law, and has the authority to adopt regulations exclusively under state authority, Section 25-7-105.1(1), C.R.S. Thus, the Commission has the statutory authority to maintain the AIR Program as a state-only rule in the Greeley area, but remove the program from the SIP for such area.

Findings Pursuant to 25-7-110.8. C.R.S.

The December 2002 changes to Regulation No. 11 merely change the federal status of the regulation;

this rule change does no have any effect on air quality or motor vehicle emission. Thus, the rule change is administrative in nature, and is not based on scientific evidence demonstrating that it will improve air quality.

In evaluating the available options, the Commission considered the option of repealing the AIR Program for the Greeley area. Such an option would likely comply with the minimum federal requirements in a more cost-effective manner.

Notwithstanding the cost effectiveness of the repeal of the program, the Commission has retained the AIR Program as a state-only program. This is the same approach the Commission took for the City of Ft. Collins in July 2002. The retention of the regulation as a state-only rule will provide an opportunity for the North Front Range Transportation and Air Quality Planning Council to explore planning options for the region as a whole.

**XII. AMENDMENTS ADOPTED SEPTEMBER 18, 2003.**

Basis and Purpose

The purpose of this rulemaking action is to implement House Bill 2003-1016 and House Bill 2003-1357. The bills revised sections 42-4-309 and 42-4-310, C.R.S. to allow the sale and registration of used motor vehicles without an emissions inspection if the motor vehicle is less than three years old, and to provide that motor vehicle dealers shall not be required to have vehicles inspected more than once a year.

Federal Requirements

The federal rules do not require an inspection upon vehicle sale or transfer. The relevant federal requirement is the general requirement for the state implementation plan to contain the control measures necessary to demonstrate maintenance of the national ambient air quality standards. Although the pre-existing requirement for an emissions test upon sale or transfer of a vehicle is included in the state implementation plan, Colorado did not take any emissions reduction credit for such a requirement. Thus, we may revise the state implementation plan to implement HB03-1016 and HB03- 1357.

Statutory Authority

The Commission promulgates these regulatory changes pursuant to its authority to promulgate such regulations as may be necessary to implement the program set out in section 42-4-306(1), C.R.S.

Findings Pursuant to 25-7-110.8. C.R.S.

The requirements of 25-7-110.8 do not apply to the September 2003 rule revisions because these revisions do not establish new requirements intended to reduce air pollution. Instead, the rule revisions relax pre-existing requirements as provided in HB03-1016 and HB03-1357.

**XIII. AMENDMENTS ADOPTED DECEMBER18, 2003.**

Basis and Purpose

The purpose of this revision is to postpone the change in emissions standards scheduled to take effect on January 1, 2004 for 1996 and newer light-duty vehicles. The standards scheduled to take affect on January 1, 2004 were overly stringent, and were likely to result in an unacceptable number of "false failures". A false failure occurs when a vehicle fails the emissions test even though there is nothing wrong with the vehicle. The effect of the rule change is to maintain the status quo pending a SIP revision based on MOBILE6. The Commission will reconsider the standards appropriate for 1996 and newer light-duty vehicles when it revises the carbon monoxide maintenance plan for the Denver metropolitan area.

The specific authority to establish emissions standards is set out at section 42-4-306(6)(b), C.R.S.

The requirements of section 25-7-110.8, C.R.S. do not apply to the November 2003 rule revision because the revision does not establish new requirements intended to reduce air pollution. Instead, the rule revision relaxes the emissions standards for 1996 and newer vehicles.

**XV. AMENDMENTS ADOPTED DECEMBER 18, 2003.**

Basis and Purpose

The purpose of this rulemaking action is to remove the El Paso County component of the automobile inspection and maintenance program ("AIR Program" ) from the federally enforceable state implementation plan (SIP). Although the AIR Program will continue to apply in El Paso County as state law, the Commission will schedule another hearing to consider terminating the program in El Paso County once the Division has evaluated the impact such termination may have on ozone concentrations.

The AIR program is no longer necessary to comply with minimum federal requirements in El Paso County. The retention of a state-only program is arguable more stringent than the minimum federal requirements, but it is reasonable and appropriate to retain the program while the Division evaluates the impacts the program may have on ozone concentrations.

Statutory Authority

Section 25-7-105, C.R.S. grants the Commission the authority to adopt a comprehensive SIP. In addition, section 25-7-105.1(1), C.R.S. authorizes the Commission to adopt rules exclusively under state authority which shall not be part of the SIP.

Findings Pursuant to 25-7-110.8. C.R.S.

The December 2003 changes to Regulation No. 11 merely change the federasl status of the regulation. This rule change is administrative in nature and will not have any effect on air quality or motor vehicle emissions.

**XVI. AMENDMENTS ADOPTED MARCH 12, 2004.**

Basis and Psurpose

The revisions to Regulation No. 11 reduce the maximum number of vehicles that may be exempted from conventional emissions testing at an inspection station through the use of the Clean Screen Program. Regulation No. 11 previously provided that up to 80% of the fleet may be evaluated by the Clean Screen Program, beginning February 28, 2005. However, it appeared at the hearing that the goal of screening 80% of the vehicle fleet with the Clean Screen Program was unrealistic; a more realistic goal would be to screen 50% of the vehicle fleet. Revising the Regulation and the SIP to reflect this resality will result in an emission reduction benefit for purposes of the attainment demonstration.

The Commission also repealed provisions stating that the $NO_x$ standards and gas cap test requirements were not to be included in the State Implementation Plan. Previously, such requirementss were not necessary to the SIP because the State took no credit for the measures for SIP modeling purposes. The requirements are, however, necessary for the attainment demonstration set out in the Early Action Compact Ozone Action Plan for the 8-hour Ozone Control Area. Therefore, these requirements must now be incorporated into the SIP.

The statutory authority for the rule change is set out at section 42-4-306(23)(a), C.R.S. This rule revision is based on the recognition that practical and technical hurdles make it unlikely that the clean screen program will achieve the 80% level previously authorized by the regulation. The amendment is not

intended to reduce pollution, rather the change is necessary so that the SIP will reflect the true nature of the clean screen program. Since this change is not intended to reduce air pollution, the requirements of 25-7-110.8 do not apply.

**XVII. AMENDMENTS ADOPTED FEBRUARY 17, 2005.**

Basis and Purpose

The purpose of this rulemaking is to specify that the AIR program will no longer apply in El Paso, Larimer, and Weld counties.

Federal Requirements

Federal law no longer requires the basic program in El Paso, Larimer, and Weld counties because the Commission has submitted carbon monoxide maintenance plans for such areas showing maintenance of the NAAQS without the AIR program.

Statutory Authority

The Commission promulgates these regulatory changes pursuant to its authority to promulgate such regulations as may be necessary to implement the program set out in section 42-4-306(1), C.R.S. Specific statutory authority to specify that the AIR program no longer applies in El Paso, Larimer, and Weld counties is set out in section 42-4-316(1), C.R.S.

Findings Pursuant to 25-7-110.8, C.R.S.

The requirements of 25-7-110.8 do not apply to the February 2005 rule revisions because these revisions do not establish new requirements intended to reduce air pollution. Instead, these revisions terminate the program in El Paso, Larimer, and Weld counties.

**XVIII. AMENDMENTS ADOPTED NOVEMBER 17, 2005.**

The purpose of this rulemaking is to implement provisions contained in HB05-1214 that eliminate the inspection requirement for vehicles that have not yet reached their fourth model year registering in the IM Program area for the first time. Another purpose of this revision is to prevent a change in emissions standards scheduled to take effect on January 1, 2006 for 1996 and newer light-duty vehicles. The standards scheduled to take affect on January 1, 2006 were overly stringent, and were likely to result in an unacceptable number of “false failures” . A false failure occurs when a vehicle fails the emissions test even though there is nothing wrong with the vehicle. The effect of the rule change is to maintain the status quo. The provisions amended in this rule change are not more stringent than federal requirements.

Statutory Authority

The Commission promulgates these regulatory changes pursuant to its authority to promulgate such regulations as may be necessary to implement the program set out in section 42-4-306(1), C.R.S. and the authority to set emissions standards provided by section 42-4-306(6)(b).

Findings Pursuant to 25-7-110.8, C.R.S.

The requirements of 25-7-110.8 do not apply to the November 2005 rule revisions because these revisions do not establish new requirements intended to reduce air pollution. Instead, these revisions implement state statute and lessen the cost and burden of the automobile inspection and readjustment program.

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## Editor’s Notes

## History