COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

NOTICE OF RULE MAKING HEARING

Pursuant to Colorado Revised Statutes, Title 12, Article 42.5 and Title 24, Article 4, CRS, you are hereby advised that the Colorado State Pharmacy Board will hold a public rule making hearing on Thursday, July 19, 2018 at 9:30 a.m., at 1560 Broadway, Conference Room 110 D, Denver, Colorado 80202, for consideration of the following:

Hearing Regarding Repeal, Modification, Amendment, Revision or Adoption of portions of:

Rule 3.05.00	(3 CCR, 719-1)
Rule 5.01.31	(3 CCR, 719-1)
Rule 5.01.40	(3 CCR, 719-1)
Rule 5.01.50	(3 CCR, 719-1)
Rule 11.03.05	(3 CCR, 719-1)
Rule 11.04.10	(3 CCR, 719-1)
Rule 11.06.10	(3 CCR, 719-1)
Rule 14.02.30	(3 CCR, 719-1)
Rule 20.00.90	(3 CCR, 719-1)
Rule 20.01.00	(3 CCR, 719-1)
Rule 21.00.20	(3 CCR, 719-1)
Rule 21.20.70	(3 CCR, 719-1)
Rule 25.00.12	(3 CCR, 719-1)
Rule 25.00.14	(3 CCR, 719-1)
Rule 25.00.16	(3 CCR, 719-1)

The proposed rules under consideration are attached to this notice and fully incorporated herein.
The reason for this rulemaking is to implement new legislation and to amend other rules as determined necessary by the Board. The Board encourages interested parties to submit written comments to the letterhead address regarding any of the above-listed rulemaking matters no later than **June 29, 2018**. In addition, at the time and place designated in this notice, the Board of Pharmacy will afford interested parties an opportunity to submit written information, data, views or arguments. The Board also will afford interested parties an opportunity to make brief oral presentations unless the Board in its discretion determines that such oral presentations are unnecessary. All submissions will be considered. The rules under consideration may be changed or modified after public comment and hearing.

BY ORDER OF THE COLORADO STATE BOARD OF PHARMACY

Wendy Anderson, Program Director
Dated this 12th day of June, 2018.

3.05.00 Pharmacist Prescribing and Dispensing Over-the-Counter Medications

3.05.10 Pharmacists, pursuant to 12-42.5-102(27), C.R.S. may prescribe and dispense certain over-the-counter medications ("OTC Medications") to recipients under the Colorado Medical Assistance Act,

3.05.20 The formulary of the eligible OTC medications is determined by the Colorado Department of Health Care Policy and Financing or its successor agency. Pharmacists may only prescribe and dispense these eligible medications pursuant to the policies established by the Colorado Department of Health Care Policy and Financing or its successor agency.

3.05.30 When prescribing such OTC medications, the pharmacist shall issue a prescription order as defined in 12-42.5-102(24)(a), C.R.S. The prescribing pharmacist's name shall be used on the prescription order as the name of the practitioner.

3.05.40 When issuing the prescription order, the pharmacist shall consult with the recipient to determine necessity and suitability of the medication for the recipient. Written documentation of the necessity and suitability of the medication shall be maintained with the prescription order.

3.05.50 Pharmacist prescribed OTC prescriptions shall require a written prescription order.

3.05.60 Written prescription orders are not eligible for prescription transfer and cannot be refilled.

3.05.70 The pharmacist shall review the recipient's drug therapy history for potential drug interactions.

3.05.80 When dispensing the medication, the pharmacist shall label the product with all labeling requirements of 12-42.5-121, C.R.S. The prescribing pharmacist's name shall be used on the label as the name of the practitioner.

3.05.90 Upon delivery of the medication to the recipient, the pharmacist shall provide consultation with the recipient or his or her caregiver as required by the Colorado Department of Health Care Policy and Financing.

3.05.95 The prescription order issued, documentation of medication necessity and suitability, and records of dispensing shall be maintained at the prescription drug outlet as required by Rule 11.00.00.

5.01.31 Within every prescription drug outlet as defined in CRS 12-42.5-102(35), there shall be one area designated as the principal compounding/dispensing area. In addition to the principal compounding/dispensing area there may be satellite compounding/dispensing areas and drug storage areas ("satellites") which are located at the same location as the principal compounding/dispensing area. The principal compounding/dispensing area and any satellite shall comply with the following conditions:

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

b. All compounding/dispensing satellites and any drug storage satellites in excess of the two permitted in subsection c below that are at the same location as the principal compounding/dispensing area must not be less than 100 continuous square feet and must be approved by the Board prior to use for compounding/dispensing.

c. In addition to the satellite areas permitted in the previous paragraph, up to two satellites at the same location may be used solely for storage of prescription drugs and controlled substances. Such drug storage satellites must possess square footage commensurate for the safe storage and removal of drugs within the affected satellites and approved by the Board prior to use.

d. Any room included within or adjacent to the principal compounding / dispensing area that is separated from the principal compounding / dispensing area by a door must meet the following:

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

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

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

e. All compounding/dispensing areas and satellites shall be well-lighted and well-ventilated with clean and sanitary surroundings devoted primarily to compounding/dispensing or drug storage. 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.

f. In every prescription drug outlet and in every satellite where compounding or dispensing is physically occurring, there shall be a minimum of 12 continuous square feet of free and clear counter space, and a minimum of 6 continuous square feet of free and clear counter space for each person engaged in compounding/dispensing as defined. These counters and surfaces shall be kept free and clear at all times for the purpose of compounding/dispensing. Any computer workstation or other equipment for the preparation of prescription labels and/or storage and retrieval of records shall be in addition to the minimum free compounding/dispensing area.

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

(2) The free floor space between shelving rows shall be not less than 24 inches; and

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

g. In every satellite used for the sole purpose of storing prescription drugs or controlled substances, there shall be:

(1) At least 24 inches of free floor space between shelving rows; and

(2) At least 30 inches of free floor space behind any counters, if counters are available.

h. 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.

i. The prescription drug outlet shall have all the technical equipment necessary for the appropriate compounding and dispensing it conducts.

j. If refrigerated drugs are stored in the principal compounding/dispensing area or in any satellite, there shall be a refrigerator, dedicated to storing only drugs, meeting the compendia requirements and with an accurate thermometer in the refrigerator. The temperature of which shall be maintained between two and eight degrees Celsius (2 and 8 degrees C.) or thirty-six and forty-six degrees Fahrenheit (36 and 46 degrees F.). The temperature shall be electronically monitored each calendar day. Records detailing instances in which temperatures fall outside the aforementioned range requirement, for any period of time, shall be maintained at the prescription drug outlet and shall be made readily available for inspection upon request by the Board or its representatives for a period of at least two years preceding the request. Such records shall include the duration of time the temperature fell outside the aforementioned range requirement, based on the best available data, and measures taken by the outlet as a result of the temperature falling outside the aforementioned range requirement.

k. If frozen drugs are stored in the principal compounding/dispensing area or in any satellite, there shall be a freezer, dedicated to storing only drugs, meeting the compendia requirements and with an accurate thermometer in the freezer. The temperature of which shall be maintained between twenty-five degrees below zero and ten degrees below zero Celsius (– 25 and – 10 degrees C.) or thirteen degrees below zero and fourteen degrees Fahrenheit (– 13 and 14 degrees F.). The temperature shall be electronically monitored each calendar day
Records detailing instances in which temperatures fall outside the aforementioned range requirement, for any period of time, shall be maintained at the prescription drug outlet and shall be made readily available for inspection upon request by the Board or its representatives for a period of at least two years preceding the request. Such records shall include the duration of time the temperature fell outside the aforementioned range requirement, based on the best available data, and measures taken by the outlet as a result of the temperature falling outside the aforementioned range requirement.

l. There shall be a professional reference library available in the prescription drug outlet. 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:

(1) A CRS Title 12, Article 42.5; the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act;

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

(3) Board rules;

(4) 21 Code of Federal Regulations ("CFR") Part 1300 to End containing Drug Enforcement Administration rules relating to controlled substances;

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

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

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

m. 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 and transcribed to writing by the pharmacist or intern.

n. 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.

o. **All prescription drug outlets shall maintain an adequate inventory of prescription drugs and shall offer adequate pharmaceutical service to the public they normally serve.**

p. **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.**

q. **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.**

r. **If a computer terminal or other device is used by pharmacy personnel outside the compounding / dispensing area, but within the same location (building) as the prescription drug outlet, when a Colorado-licensed pharmacist is in the building for the purpose of processing, gathering or storing prescription information, the pharmacist manager of the prescription drug outlet shall determine procedures for the storage and security of, the access to, and the confidentiality of patient information within the computer terminal or other device and shall be subject to Board Rule 1.00.16, the federal Health Insurance Portability and Accountability Act of 1996 and any rules promulgated pursuant to such act.**

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. These minimum requirements shall not apply within the first 120 calendar days after the prescription drug outlet has been registered by the Board if the outlet has not obtained prescription drug or controlled substance stocks.**

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

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

a. When any compounding/dispensing area of a prescription drug outlet is occupied by any employee, a pharmacist must be physically present within the same building of the prescription drug outlet. This rule shall not apply if the prescription drug outlet does not possess prescription drug or controlled substance stocks or patient information within the first 120 calendar days after the prescription drug outlet has been registered by the Board.

b. In the event a pharmacist is within the building 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 e below unless the prescription drug outlet qualifies for the exemption provided under Board Rule 5.01.50(a).

d. If more than one prescription drug outlet is located within the same building, a pharmacist shall not operate more than one outlet at the same time. If a pharmacist physically leaves one outlet for the purpose of entering into another outlet within the same building, any outlet not being physically attended to by a pharmacist shall be enclosed by a barrier as specified in paragraph e below and a non-pharmacist shall not remain inside the enclosed outlet during that time unless the prescription drug outlet qualifies for the exemption provided under Board Rule 5.01.50(a).

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

f. All entrances to every compounding/dispensing area shall be secured from unauthorized entry when the pharmacist leaves the building except as provided in Board Rule 5,01.50(a). No one other than a pharmacist shall be permitted to enter any compounding /dispensing area containing drugs, devices or patient information 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 containing drugs, devices or patient information 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 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.

g. 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.

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

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

j. 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 nursing 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 rule.

11.03.05 Perpetual Inventories of Controlled Substances. All prescription drug outlets shall at all times maintain a current, complete and accurate perpetual controlled substance inventory. All perpetual inventory of controlled substance inventories shall comply with the following:

a. Each inventory shall include, at minimum, all Schedule II controlled substances.

b. 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.

c. Regardless of the prescription drug outlet's chosen method of perpetual inventory maintenance, each perpetual inventory shall be made readily retrievable and available in both a printed and contemporaneous format immediately upon the request of the Board or its inspectors with the information required in this Board Rule 11.03.05(a) and (b).

d. If the outlet is registered with the Drug Enforcement Administration as a "hospital/clinic" or is owned and operated by a health maintenance organization (as defined in Section 10-16-102, C.R.S.), the perpetual 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.

11.04.10 **A hard copy of every prescription order shall be readily retrievable, legible, 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 substance prescription drugs and Schedule II, III, IV, and V ~~C~~controlled ~~S~~substances. Prescription orders will be deemed to be readily retrievable, legible, and available if they are filed according to the numerical sequence of the serial numbers assigned pursuant to 2.01.10, and are easily readable without the aid of any special device. If Board-approval for the electronic maintenance of prescription orders is granted, the affected prescription drug outlet shall maintain all hard copy controlled substance prescription orders in accordance with any applicable federal rules and laws. In addition to being filed in numerical sequence, three different prescription files shall be maintained: one file shall consist only of ~~s~~Schedule II controlled substance prescription orders; the second file shall consist only of ~~s~~Schedule III, IV and V controlled substance prescription orders; and the third file shall consist of all non-controlled substance prescription drug 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 LTCF 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. LTCF ~~C~~chart orders for ~~s~~Schedule III, IV, and V controlled substances shall be readily identifiable from non-controlled substance prescription drug LTCF chart orders. Schedule II controlled substance LTCF chart orders shall be retained separately from all other LTCF chart 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.

11.06.00 Receipts

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

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

a. Name of the drug;

b. Strength of the drug;

c. Dosage form if appropriate;

d. Quantity received;

e. Date received;

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

g. Name and address of the distributor;

h. Name and address of the receiving outlet;

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

j. If a schedule II controlled substance, ~~The~~ the DEA ~~form~~ Form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other. If the DEA's Controlled Substance Order System (CSOS) is used to order and receive a schedule II controlled substance, only a record of receipt compliant with this Rule 11.06.10(a) through (i) shall be maintained if the record is electronically linked to the original electronic DEA Form 222 and archived as provided in 21 Code of Federal Regulations, Section 1305.22(g).

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~~ each consultant pharmacist visit at a frequency determined pursuant to Board Rule 14.00.80(e). The inventory shall be recorded on a uniform and readily retrievable record, and this record shall be signed by the consultant pharmacist of the other outlet.

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.**

20.00.90 Responsibilities of Originating Pharmacy.

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

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

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

3. Name of pharmacist transmitting the order; and

4. The date of transmission.

5. Dispensing transactions in the shared pharmacy services process are exempt from the requirement of writing "Central Fill" on the face of the original prescription

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

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

2. Name of pharmacist transmitting the order; and

3. The date of transmission.

c. ~~Upon receipt of~~ If the prescription is received from the fulfillment pharmacy and not delivered directly to the patient from the fulfillment pharmacy, the originating pharmacy shall record the following:

1. Date of receipt;

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

3. Name of pharmacy employee accepting delivery.

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

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

20.01.00 Responsibilities of Fulfillment Pharmacy.

a. The fulfillment pharmacy shall:

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

2. Retain a record detailing the following:

i) Date the transmitted order was received;

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

iii) Date the order was fulfilled;

iv) Date prescription delivered to the originating pharmacy or delivered directly to the patient; and

v) The method of delivery.

21.00.20 Casual Sales/Distribution of Compounded Products.

a. An in-state prescription drug outlet shall only distribute a compounded product to:

(1) Practitioners licensed and located in Colorado and authorized by law to prescribe the drug;

(2) Colorado licensed/registered acupuncturists, direct-entry midwives, or naturopathic doctors who are located in Colorado and authorized by law to obtain the drug;

(3) Hospital prescription drug outlets registered and located in Colorado; or

(4) Other outlets registered and located in Colorado.

Except as provided by Rule 21.00.20(d), distribution of the compounded product pursuant to this rule shall be for the sole purpose of drug administration. In-state Prescription Drug Outlets shall not distribute compounded products outside of the state. In-state Prescription Drug Outlets shall dispense compounded products and ship them out of the state only pursuant to patient-specific prescription orders.

b. Unless otherwise allowed by state and federal law, nonresident prescription drug outlets shall not distribute compounded products into Colorado pursuant to 21 U.S.C. secs. 331(a), 353(b) and 355(a).

c. Unless otherwise allowed by state and federal law, nonresident prescription drug outlets registered in Colorado may dispense compounded products and ship them into Colorado only pursuant to valid, patient-specific prescription orders.

d. A nonresident prescription drug outlet may distribute a compounded product to a Colorado-licensed veterinarian who is located in Colorado and authorized by law to prescribe the drug only if:

i) The nonresident prescription drug outlet provides the Board with a copy of the outlet's most recent report detailing an inspection by the National Association of Boards of Pharmacy Verified Pharmacy Program, for which third-party inspection the nonresident prescription drug outlet shall obtain and pay for on an annual basis, and the Board approves the inspection report as satisfactorily demonstrating proof of compliance with the Board's own inspection procedures and standards;

ii. The nonresident pharmacy provides a copy of the most recent inspection of the nonresident pharmacy by the agency that regulates pharmaceuticals in the state of residence; and

ii) The nonresident prescription drug outlet provides the Board, on an annual basis, with a copy of the outlet's current manufacturer registration obtained from the Drug Enforcement Administration.

21.20.70 Environmental Monitoring.

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

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

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

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

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

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

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

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

f. **A pressure gauge shall be installed to monitor the pressure differential between the ISO Class 7 cleanroom and the ISO Class 8 anteroom and the anteroom and the general pharmacy area. The results shall be reviewed and documented on a daily basis. The pressure between the cleanroom and general pharmacy area shall not be less than 5 Pa (0.02-inch water column, w.c.). The pressure differential between the cleanroom and the anteroom shall be greater than the pressure differential between the anteroom and the general pharmacy area, except for the preparation of radiopharmaceuticals where there is no pressure differential.**

g. For buffer areas not physically separated from ante-areas, a velocity flow meter may be installed in place of a pressure gauge to monitor the displacement airflow to require an air velocity of 40 feet per minute or more from the buffer area across the line of demarcation into the ante-area. The results shall be reviewed and documented on a daily basis.

25.00.12 Requirements for Registration. Eligibility requirements for an SPDO include the following:

a. A current Board-issued registration of the managing prescription drug outlet that engages in the compounding, dispensing, and delivery of drugs, or provision of pharmaceutical care to residents of an LTCF;

b. The submission of a separate application by the managing prescription drug outlet on behalf of the SPDO for a SPDO registration, on a form provided by the Division of Professions and Occupations. The managing prescription drug outlet shall submit an application for each individual SPDO to which the managing prescription drug outlet will provide stock drugs;

c. A Drug Enforcement Administration registration specifically assigned to the SPDO if the managing prescription drug outlet provides stock controlled substances to the SPDO;

~~**d. Successful completion of a pre-registration inspection of the SPDO by the Board or its inspectors;**~~

~~e~~d. A pharmacist manager who, in addition to being responsible for the operations of the managing prescription drug outlet in compliance with all state and federal laws and rules, is responsible for the operations of the SPDO in compliance with all provisions of rule 25.00.00; and

~~f~~e. A secure AD that prevents the diversion of drugs and that limits the access to drugs within the AD only to those persons whom have been given permission to access the AD.

25.00.14 Scope of Practice.

a. An SPDO shall maintain and operate an AD for the purpose of storing drug stocks.

b. The managing prescription drug outlet shall ensure that all medications stocked in the AD are either in unit dose form, single dose packages, or packaged as such or in customized medication packs prior to release from the AD for administration to a patient. All records of packaging shall be maintained at the managing prescription drug outlet.

c. Medication that is packaged and labeled for a specific patient by an AD at the SPDO is the responsibility of the specific pharmacist that conducted the final verification of the prepackaged automated cassette pertaining to that specific drug at the PDO. The pharmacist that conducted the final verification of the prepackaged automated cassette pertaining to that specific drug at the PDO shall be deemed to be the pharmacist responsible for the final evaluation of all prescriptions dispensed from the automated cassette within the AD at the SPDO.

~~c~~d. An SPDO shall only utilize stock prescription drugs or controlled substances it receives from the managing prescription drug outlet for the purpose of drug administration, and not for the purpose of further dispensing.

25.00.16 Records and Recordkeeping.

a. The managing prescription drug outlet shall be exempt from any casual sale limitations specified in 12-42.5-102(6) C.R.S. only to the extent of distributing drug stocks to an SPDO.

b. Records of drug distribution from the managing prescription drug outlet to the SPDO shall be retained at the managing prescription drug outlet and shall be readily available for inspection by the Board or its inspectors for at least two years from the date of distribution. These records shall be maintained separately from all other records of distribution to Board-registered entities which are not SPDOs or individual practitioners authorized by law prescribe the drugs. The record of distribution shall include the following:

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 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 prescription drug outlet;

8. The name and address of the receiving SPDO;

9. If a controlled substance is distributed, the record shall also indicate the DEA registration number of the distributing prescription drug outlet and the receiving SPDO;

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

11. The identity of the person in the prescription drug outlet who issued the drug; and

12. The identity of the person who placed the drug into the SPDO's AD.

c. A duplicate copy of the record of distribution outlined in Rule 25.00.16(b) shall be maintained at the SPDO in a readily retrievable manner for at least two years from the date of receipt. This record shall serve as the SPDO's record of receipt.

d. Records of use from the AD shall be retained at the managing prescription drug outlet and shall be readily available for inspection by the Board or its inspectors for at least two years from the date of latest use transaction. The record of use shall include the following:

1. The name of the patient;

2. **The name of the practitioner;**

3. **Date removed;**

4. **The name, strength and dosage form of the drug removed;**

5. **The quantity of the drug removed; and**

6. **The identity of the person at the SPDO that removed the drug.**

e. **~~Biennial Controlled Substance Inventory.~~ A complete and exact inventory of all stocks of controlled substances shall be conducted at each SPDO at least once every ~~two years~~ month. The inventory shall be recorded on a uniform and readily retrievable record, and this record shall be signed by the pharmacist manager of the managing prescription drug outlet or another pharmacist as delegated by the pharmacist manager. The inventory shall include the date and time of day the inventory was conducted. A copy of this recorded inventory shall be maintained and readily available for inspection at both the managing prescription drug outlet and SPDO for at least two years from the date the inventory was conducted. This inventory record shall be maintained separately from all other recorded inventories of the managing prescription drug outlet.**