

DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

STATE BOARD OF 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.

1.00.16 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 pharmacy technicians, 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 imply 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. Except as specified in section 12-280-138, C.R.S., a pharmacist shall provide patient counseling on new medication therapy and, based on the pharmacist's professional judgement and due diligence, may provide patient counseling for any other prescription.

- a. If a pharmacist is unable to provide patient counseling orally due to language barriers, a pharmacist shall use whatever alternative means are necessary to assure the patient is properly counseled as to the medication the patient is provided. This may include, but may not be limited to, written communication in the corresponding language that the patient understands.
 - b. Any refusal on the part of the patient to accept patient counseling shall be clearly documented in the corresponding record, which may include an electronic record, directly linked to each affected corresponding order and such documented refusal shall be readily retrievable and available for inspection by the Board or its inspectors for at least two years following the date of the refusal.
- 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.
- 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 Except as provided in sections 12-280-103(54)(b)(III) and 25.5-2.5-201 through 25.5-2.5-208, C.R.S., a prescription drug outlet shall ensure that all prescription drugs and controlled substances are procured from another entity or person registered by the Board. 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 section 12-280-131(2), C.R.S.
- 1.00.25 Colorado-licensed pharmacists with appropriate training may order and administer CLIA-waived tests, including serology tests that have authorized by the Food and Drug Administration (FDA), or equivalent regulatory authorization, subject to the disclaimers and limitations required by the FDA for such tests.
- 1.00.26 REQUIRED DISCLOSURE TO PATIENTS – CONVICTION OF OR DISCIPLINE BASED ON SEXUAL MISCONDUCT (Section 12-30-115, C.R.S.)**
- A. On or after March 1, 2021, a provider shall disclose to a patient, as defined in section 12-30-115(1)(a), C.R.S., instances of sexual misconduct, including a conviction or guilty plea as set forth in section 12-30-115 (2)(a), C.R.S., or final agency action resulting in probation or limitation of provider ability to practice as set forth in section 12-30-115(2)(b), C.R.S.
 - B. Form of Disclosure: The written disclosure shall include all information specified in section 12-30-115(3), C.R.S., and consistent with the sample model disclosure form as set forth in Appendix D to these rules. The patient must, through his or her signature on the disclosure form, acknowledge the receipt of the disclosure and agree to treatment with the provider.

- C. Timing of Disclosure: This disclosure shall be provided to a patient the same day the patient schedules a “professional services” appointment with the provider. If an appointment is scheduled the same day that services will be provided, the disclosure must be provided in advance of the treatment.
1. The written disclosure and agreement to treatment must be completed prior to each treatment appointment with a patient/client, unless the treatment will occur in a series over multiple appointments or a patient/client schedules follow-up treatment appointments.
 2. For treatment series or follow-up treatment appointments, one disclosure prior to the first appointment is sufficient, unless the information the provider is required to disclose pursuant to section 12-30-115, C.R.S., has changed since the most recent disclosure, in which case an updated disclosure must be provided to a patient/client and signed before treatment may continue.
 3. For the purpose of this Rule 1.00.25, “professional services” shall include face-to-face counseling including, but not limited to, the administration of drugs and vaccines, collaborative pharmacy practice, and allowable testing and diagnostics.
 4. A provider who does not have a direct treatment relationship or have direct contact with the patient is not required to make the disclosure required by this section.
- D. As set forth in section 12-30-115(3)(e), C.R.S., the requirement to disclose the conviction, guilty plea, or agency action ends when the provider has satisfied the requirements of the probation or other limitation and is no longer on probation or otherwise subject to a limitation on the ability to practice the provider's profession.
- E. A provider is not required to provide the written disclosure **BEFORE** providing professional services to the patient in the following instances as set forth in section 12-30-115(4), C.R.S.:
1. The patient is unconscious or otherwise unable to comprehend the disclosure and sign an acknowledgment of receipt of the disclosure pursuant to section 12-30-115(3)(d), C.R.S., and a guardian of the patient is unavailable to comprehend the disclosure and sign the acknowledgment;
 2. The patient visit occurs in an emergency room or freestanding emergency department or the visit is unscheduled, including consultations in inpatient facilities; or
 3. The provider who will be treating the patient during the visit is not known to the patient until immediately prior to the start of the visit.
- F. The provider who does not have a direct treatment relationship or have direct contact with the patient is not required to make the disclosure required by this section.

[Appendix D is located at the end of the Rules]

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 section 12-280-120(11), C.R.S.
- 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 date the order was compounded and dispensed;
- b. The assigned serial number (hospital chart orders are exempt from this requirement);
- c. The quantity dispensed if differs from the quantity ordered (LTCF chart orders are exempt from this requirement provided this information is recorded within another appropriate uniformly maintain and readily retrievable permanent record of the dispensing pharmacy);
- d. In the case of a controlled substance order, the patient address, prescriber address, and prescriber's Drug Enforcement Administration (DEA) registration;
- e. Patient address, prescriber address, and prescriber DEA registration number need not appear on any type of order for a non-controlled substance prescription; and
- f. Minor adaptations to an order as allowed pursuant to section 12-280-125.3, C.R.S., which shall detail the date and identity of the pharmacist making the minor adaptations.

2.01.20 Additional Information. The following shall also appear on the prescription or LTCF chart order, or corresponding readily available and retrievable electronic record of 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 or unique identifier 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).
 - (5) In addition to the information provided in this Rule 2.01.20(c), when a substitution is made on a prescription order pursuant to section 12-280-125(1)(a.5), C.R.S., the dispensing pharmacist shall clearly document that the prescription was an intentional substitution within the same therapeutic drug class by writing the words "Intentional Therapeutic Drug Class Substitution" or a substantially equivalent statement on the date the substitution occurred.

- c. In the case of a chart order for a hospitalized patient (hospital chart order), the following information need not necessarily appear on the chart order, provided that such information is recorded on another appropriate, uniformly maintained and readily retrievable permanent record which reflects:
 - (1) The identity of the pharmacist making the initial interpretation;
 - (2) The identity of the pharmacist making the final evaluation each time a drug is dispensed, if different from the pharmacist making the initial interpretation;
 - (3) The quantity dispensed and
 - (4) The date of dispensing.
 - (5) Any record of a controlled substance dispensed pursuant to a chart order for an individual patient shall be visually identifiable from records of non-controlled substances.

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

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

2.01.50 Transfer of Prescription Orders Between Prescription Drug Outlets.

- a. A prescription label or a written copy of a prescription order from another pharmacy may be used for informational purposes only and shall not be considered to be a valid prescription order. A pharmacist, pharmacy intern, or pharmacy technician 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, pharmacy intern, or pharmacy technician may orally transfer prescription order information for non-controlled substances for the purpose of dispensing a prescription.
- 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, pharmacy intern, or pharmacy technician shall comply with rule 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 rules 2.01.52 and 2.01.53 (1)-(10). In the case of electronic transfers, the transferring and receiving pharmacist, pharmacy intern, or pharmacy technician may be the same person.
 - (3) In the case of prescription drug outlets that access and share the same data storage device and that can electronically retrieve all necessary 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 refill 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. Verbal transfers of CIII-CV electronically submitted prescriptions are permitted in Colorado.
- e. The one-time transfer of an electronic prescription for a schedule II-V controlled substance, for initial dispensing, is permissible if the transfer information is communicated between two licensed pharmacists; the transferred prescription remains in its electronic form; and the prescription information is not altered during the transmission.
- f. A pharmacist may authorize pharmacy technician or pharmacy intern to electronically transfer an order, for the purpose of redispensing said order, provided that the electronic transfer is between two compatible computer systems and no changes are made. The pharmacist shall be identified on the transfer record as required by 2.01.52 and 2.01.53.

2.01.52 The transferring pharmacist, pharmacy intern, or pharmacy technician 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, license or certification number, initials, or secure electronic identifier;
 - (2) The name, license number, initials, or secure electronic identifier of the receiving pharmacist or pharmacy intern or pharmacy technician;
 - (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 rule 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 rule.

2.01.53 The pharmacist, pharmacy intern, or pharmacy technician receiving the transferred prescription order information shall:

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 rule 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, license or certification number, initials, or secure electronic identifier of the transferring pharmacist, pharmacy intern, or pharmacy technician;
- (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 Drug Enforcement Administration number of the transferring prescription drug outlet, and the practitioner's Drug Enforcement Administration number.

2.01.54 The transferring prescription drug outlet shall retain the original prescription order as required by Rule 11.04.10.

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

2.01.56 The pharmacist, pharmacy intern, or pharmacy technician 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.

2.01.59 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 Rule 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, pharmacy intern, or pharmacy technician 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, pharmacy intern, or pharmacy technician 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 Rule 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 Rule 2.01.52(c).

3.00.00 DISPENSING.

3.00.10 Limitations. Except as provided in section 12-280-123(2), C.R.S., no order shall be dispensed or refilled after one year from the date of issue by the practitioner.

3.00.20 Medical Need.

- (a) 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 section 12-280-126, C.R.S.
- (b) One additional bottle of a prescription eye drop may be dispensed to a patient if the following conditions are met:
 1. The corresponding patient's health benefit plan provides coverage for the prescription eye drops;
 2. The additional bottle is requested by the insured or the health care provider at the time the original prescription is dispensed;
 3. The original order states that one additional bottle is needed by the insured for use in a day care center, school, or adult day program;
 4. The additional bottle is limited to one additional bottle every three months; and

5. The total number of bottles dispensed does not exceed the total number of bottles prescribed as stated on the original order when accounting for authorized refills assigned to the original order by the prescriber, if applicable.
- (c) A prescription eye drop may be refilled if the following conditions are met:
1. The refill is requested by the insured at least twenty-one days for a thirty day supply of eye drops, forty-two days for a sixty day supply of eye drops, or sixty-three days for a ninety day supply of eye drops, from the later of the date that the original prescription was dispensed to the insured or the date that the last refill of the prescription was dispensed to the insured; and
 2. The original prescription order states that additional quantities of prescription eye drops are needed and the refill requested by the insured does not exceed the number of additional quantities needed.
- (d) 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. Compounded prescription drugs distributed to veterinarians for "office stock" as defined in section 12-280-121(5)(b), C.R.S., must comply with the requirements of Rules 11.00.00 and 21.00.00.
- 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 know that the order for such drug was issued without a valid preexisting patient-practitioner relationship. Such relationship need not involve an in-person encounter between the patient and practitioner if otherwise permissible under Colorado law. A pharmacist may, in good faith, prescribe or dispense an opiate antagonist pursuant to an order that was issued without a valid preexisting patient-practitioner relationship that is approved by the Federal Food and Drug Administration for the treatment of a drug overdose.
- 3.00.22 The prescribing or dispensing of an opiate antagonist, as described in Rule 3.00.21, by a pharmacist shall not constitute unprofessional conduct pursuant to section 12-280-126, C.R.S., if he or she prescribed or dispensed the opiate antagonist in good faith pursuant to an order or standing orders and protocols issued to or for individuals or entities described in section 12-30-110, C.R.S.
- a. Each prescription drug outlet shall maintain, in a uniform and readily retrievable manner for at least two years from the date of latest transaction related to a pharmacist initiated order or standing order, the following record detailing the dispensing of an opioid antagonist pursuant to a pharmacist initiated order or standing order:
- 1) The full name of the patient, person who is in a position to assist a person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event, first responder, unit of local government, or harm reduction organization receiving the drug;
 - 2) The full address of the first responder, unit of local government, or harm reduction organization receiving the drug;
 - 3) The name, strength and dosage form of the drug dispensed;
 - 4) The quantity of drug dispensed; and

- 5) The date of dispensing.

3.00.23 Dispensing without an order.

- a. A pharmacist may dispense an emergency supply of a chronic maintenance drug, as defined in section 12-280-103(9.5)(a) and (b), C.R.S., to a patient without a current, valid order under the conditions set forth in section 12-280-125.5, C.R.S. When an emergency dispensing occurs, the dispensing pharmacist, or his or her designee, shall immediately notify the practitioner of record related to the emergency dispensing, in writing, detailing the:
 - (1) Name, address, and telephone number of dispensing pharmacy;
 - (2) Name, strength, dosage form, directions, and quantity of drug dispensed;
 - (3) Name of patient and corresponding patient's date of birth; and
 - (4) Date of emergency dispensing.
- b. Records related to the dispensing of an emergency supply of a chronic maintenance drug shall be detailed and maintained in the same manner as all other dispensing transactions in compliance with all applicable provisions of Board Rules 2.00.00, 3.00.00, 11.00.00, 21.00.00, and 26.00.00.

3.00.25 First Dose Dispensing. A pharmacist at a prescription drug outlet may dispense up to a seventy-two hour supply of a non-controlled substance prescription drug to an LTCF resident pursuant to a duplicate copy of an LTCF chart order provided by another prescription drug outlet for the purpose of providing immediate patient care, on a one time per order basis, if the following conditions are met:

- a. The receiving prescription drug outlet records on the prescription order the name and address of the originating prescription drug outlet and the date the order was received by the receiving prescription drug outlet;
- b. The receiving prescription drug outlet maintains the order as a prescription order and complies with all requirements for prescription orders specified in Rules 2.01.10 through 2.01.40, 3.00.10 through 3.00.51, and 11.04.10; and
- c. The originating prescription drug outlet records on the LTCF chart order the name and address of the receiving prescription drug outlet and the date the order was provided to the receiving prescription drug outlet.

3.00.27 Outlet to Outlet Drug Reconstitution. A pharmacist at a prescription drug outlet may reconstitute a prescription originally dispensed in an unreconstituted form pursuant to a patient-specific order at another prescription drug outlet or nonresident prescription drug outlet provided the following conditions are met:

- a. The prescription is delivered directly from the originating outlet to the receiving outlet;
- b. The prescription is at no time in the physical possession of the patient until after the prescription has been reconstituted;
- c. The prescription is reconstituted according to the corresponding manufacturer's directions;

- d. The prescription is not a controlled substance;
- e. The pharmacist at the receiving outlet does not alter the prescription or its original labeling in any way other than to reconstitute, re-label for re-dispensing for administration, and properly store the prescription; and
- f. The originating outlet is ultimately accountable to the Board for the accurate dispensing of the original prescription, and the receiving outlet is ultimately accountable for the accurate reconstitution and re-dispensing of the prescription.

3.00.30 Labeling.

- a. 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.
- b. When a prescription drug is dispensed to a patient for outpatient use and contains an opioid that is not prescribed for the treatment of a substance use disorder or is a partial opioid antagonist, the label or container shall bear a notification that states, or is substantially equivalent to: "Caution: Opioids carry a risk of overdose and addiction."

3.00.40 Expiration Dating. No drug or device shall be dispensed which will be outdated prior to utilization by the consumer, based on the practitioner's directions for use.

3.00.50 Initial Interpretation and Final Evaluation.

- a. Initial interpretation means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/manual transcription and for drug regimen review.
- b. Final evaluation means the review of the final prescription to ensure that the ordered medication is properly prepared and placed in a suitable container with appropriate labeling. The pharmacist(s) conducting the final evaluation shall be held accountable for assuring that the identity of the drug that appears on the prescription label corresponds with identity of drug contained therein. When refills are dispensed, the pharmacist conducting the final evaluation shall be held accountable for the appropriate dispensing of refills including all drug utilization reviews as they pertain to refill dispensing.
- c. Drug regimen review includes but is not limited to the evaluation of order(s) and patient records(s) for:
 - 1) Known allergies;
 - 2) Rational therapy and contraindications;
 - 3) Reasonable dose, duration of use, and route of administration considering age, gender, and other patient factors;
 - 4) Reasonable directions for use;
 - 5) Potential or actual adverse drug reactions;
 - 6) Drug-drug interactions;
 - 7) Drug-food interactions;

- 8) Drug-disease contraindications;
 - 9) Therapeutic duplication;
 - 10) Proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and
 - 11) Abuse/misuse.
- d. A pharmacist shall conduct an initial interpretation of each new order and a pharmacist shall conduct the final evaluation of each order dispensed. When refills are dispensed, the pharmacist making the final evaluation shall be held accountable for the appropriate dispensing of refills. The pharmacist manager shall be held accountable for the maintenance of all appropriate records.
 - e. The pharmacist making the initial interpretation and final evaluation on prescription or LTCF chart orders shall be identified by either license number, initials, name, or secure electronic identifier on a uniformly maintained, readily retrievable document. The uniformly maintained, readily retrievable document shall bear the license number, initials, name, or secure electronic identifier of any additional pharmacists involved in the dispensing of the order. The pharmacist conducting the initial interpretation and final evaluation may be the same person.
 - f. In the case where the computer software utilized is not password protected, the initial interpretation and final evaluation shall be maintained in a handwritten format bearing the license number, initials, or name of the responsible pharmacist. In addition, the identification of any other pharmacists involved in the dispensing shall be maintained in the same handwritten format.

3.00.51 Records of Initial Interpretation and Final Evaluation.

- a. Records detailing both the initial interpretation and final evaluation shall be retained at the prescription drug outlet for each prescription dispensed and for at least two years from the date of any transaction pertaining to the order. These records shall include at least the following:
 - 1) The license number, initials, name, or secure electronic identifier of the pharmacist conducting the initial interpretation for each new order;
 - 2) The license number, initials, name, or secure electronic identifier of the pharmacist conducting the final evaluation for each new and refill prescription; and
 - 3) The specific date on which each initial interpretation and final evaluation occurred. In the event the initial interpretation and final evaluation for a new order are conducted on separate dates, both dates shall be recorded to state specifically when both occurred.
- b. Each outlet shall maintain, in written format, a notice detailing how initial interpretations and final evaluations are documented in the outlet. Such notice shall include and comply with the following:
 - 1) The manner in which initial interpretations are recorded and maintained in the outlet for all new orders.

- 2) The manner in which final evaluations are recorded in the outlet for all new and refill prescriptions.
- 3) A statement that all pharmacy personnel involved in the dispensing of prescriptions have the ability to print, upon request, a record detailing the initial interpretation for each new prescription dispensed and final evaluation for each new and refill prescription dispensed.
- 4) Such written notice shall be signed and dated or electronically approved if version and approval histories are available by the pharmacist manager. In the event the pharmacist manager changes, the incoming pharmacist manager shall review, electronically approve, or sign and date the notice within seventy-two hours of assuming the duties of pharmacist manager. In the event there is a lapse between the time one pharmacist manager ceases the duty and another assumes the duty, the previous method of recording initial interpretations and final evaluations shall remain in effect.
- 5) If there are any changes to the outlet's method of documenting initial interpretations and final evaluations, a new written notice detailing the requirements of sections 1, 2, 3, and 4 above shall be executed. This notice shall detail the effective date of change.
- 6) The outlet shall post these notices on a wall directly next to the outlet's most current Board registration or electronically publish a secure version of the notice.
- 7) These notices shall be retained at the outlet for a period of three years from the date last utilized.
- 8) In the event such notices are not posted or electronically published, the pharmacist manager shall be held accountable for the failure to post the required notice and any dispensing errors. In the event such notices are not posted during the period of time between one pharmacist manager leaving the position and another assuming the position, the outlet shall be held accountable for the failure to post the required notice and any dispensing errors.

3.00.55 Prescription Flavoring. A flavor additive may be incorporated into a non-sterile prescription under the following conditions:

- a. The patient, patient's caregiver, or practitioner who authorized the original prescription shall authorize the flavoring of each new and, if applicable, refilled prescription;
- b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug.
- c. No expired flavor additive shall be incorporated into a prescription. No flavor additive shall be incorporated which will expire prior to utilization by the patient, based on the practitioner's directions for use.
- d. For flavoring additives that do not have expiration dates assigned by the manufacturer or supplier, a pharmacist shall clearly and legibly label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the flavoring additive. In no event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container.

- e. The following information shall be recorded and maintained in a suitable hard-copy or electronic dispensing record for a period of two years from the date of flavoring the corresponding new or refilled prescription. This record shall be made available, in printed form, for the Board or its representatives immediately upon the request of the Board or its representatives.
 - 1) Additive's flavor;
 - 2) Flavor additive's manufacturer
 - 3) Flavor additive's lot number (if available); and
 - 4) Flavor additive's expiration date.
- f. The pharmacist responsible for conducting the final evaluation of a new or refilled prescription shall also be responsible for the flavoring of the prescription as specified in subsections a., b., and c. of this Rule 3.00.55.
- g. The pharmacist manager shall be responsible for subsection d. of this Rule 3.00.55 and the maintenance of records as specified in subsection e. of this Rule 3.00.55.

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 section 12-280-125, C.R.S. 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 pharmacy technicians. A pharmacist shall be responsible for pharmacy technicians and shall at all times comply with section 12-280-118(5), C.R.S.

3.00.75 The placement of a prescription into another outer container and the labeling of the container with the patient's name or any other identifying information constitutes the "Practice of Pharmacy" as a function of preparation, packaging, labeling and delivery under section 12-280-103(39), C.R.S. Individuals who perform this function shall be included in the ratio of pharmacy technicians or interns a pharmacist is permitted to supervise pursuant to 12-280-122(1), C.R.S.

3.00.80 Return or Exchange of Drugs, Prescriptions, Medical Devices, and Medical Supplies for Dispensing or Donation.

3.00.81 Definitions.

For the purposes of this Rule 3.00.00, the following definitions apply:

- a. "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.
- b. "Correctional facility" means a facility under the supervision of the United States, the Department of Corrections, or a similar state agency or department in a state other than Colorado in which persons are or may be lawfully held in custody as a result of conviction of a crime; a jail or an adult detention center of a county, city, or city and county; and a private contract prison operated by a state, county, city or city and county.

- c. "Customized patient medication package" means a package which contains two or more drugs.
- d. "Licensed Facility" means any of the following facilities licensed by the Colorado Department of Public Health and Environment: community mental health center, acute treatment unit, hospital unit, inpatient hospice, nursing care facility, assisted living residence, or long-term care facility.
- e. "Medical Device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required to be labeled pursuant to 21 CFR Part 801.
- f. "Medical Supply" means a consumable supply item that is disposable and not intended for reuse.
- g. "Nonprofit Entity" means a Board registered prescription drug outlet or other outlet which has nonprofit status, or an out-of-state entity with legal authority to both possess a prescription drug and receive a donated prescription drug distributed from a Board-registered outlet in the state of Colorado.
- h. "Originating Prescription Drug Outlet" means the prescription drug outlet which initially dispensed the prescription for a resident of a facility.
- i. "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.
- j. "Single dose package" means a package which contains a quantity of a drug intended for administration as a single dose.
- k. "Traditional dispensing system" means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.
- l. "Unique identifier" means an implicit or explicit unique identifier from which the originating prescription number can be determined.
- m. "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.
- n. "Unit dose package" means a package which contains one pharmaceutical unit.
- o. "Unit of issue package" means a package which provides multiple units of doses but separated in a medication card or other specifically designed container.

3.00.82 General Provisions

- a. No prescription drug outlet shall accept returned or donated prescriptions, medical devices, or medical supplies for dispensing, or donation except in the following situations:

- 1) A prescription drug outlet that complies with Rules 3.00.82 through 3.00.89 may accept prescriptions, medical devices, and medical supplies for return, dispensing, and donation.
- 2) A hospital prescription drug outlet may accept prescriptions and drugs for dispensing 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:
 - (a) 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 Rule 2.01.20(c); or
 - (b) 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:
 - (I) The name of the drug;
 - (II) The strength of the drug;
 - (III) The dosage form of the drug if appropriate;
 - (IV) The quantity of the drug;
 - (V) The location within the facility to which the drug was originally distributed; and
 - (VI) The date of the return.
- b. No prescription drug returned for redispensing or donation from a facility or donated by a prescription drug outlet shall be redispensed if it expires prior to utilization by the consumer based on the prescribing practitioner's directions for use.
- c. Rules 3.00.80 through 3.00.89 do not apply to the Colorado Cancer Drug Repository.

3.00.83 Entities Eligible to Donate or Return Prescriptions.

The following may donate or return drugs:

- a. A correctional facility as defined in Rule 3.00.81(b), a licensed facility as defined in Rule 3.00.81(d), or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., may return prescriptions to a prescription drug outlet.
- b. A correctional facility, a licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., may donate prescriptions to a nonprofit entity as defined in Rule 3.00.81(g) or to a practitioner authorized by law to dispense the prescription.
- c. A prescription drug outlet may donate a returned or donated prescription to a nonprofit entity as defined in Rule 3.00.81(g) or to a practitioner authorized by law to dispense the prescription.

3.00.84 Eligibility for Return or Donation.

- a. For all prescriptions, medical devices, or medical supplies accepted for return or donation, the prescription drug outlet must ensure that the prescription, medical device, or medical supply was properly stored prior to return or donation. This includes storage at the facility, and shipment to and from the facility.
- b. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are eligible for return or donation are as follows:
 - 1) Drugs which are liquid and the vial is still sealed and properly stored;
 - 2) Drugs that have been individually packaged and the packaging has not been damaged; and
 - 3) Drugs that are in the original, unopened, sealed, and tamper-evident unit dose package, unit of issue package, or unit dose dispensing system.
- c. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are not eligible for Return or Donation are as follows:
 - 1) Any drug declared to be a controlled substance under any state or federal law or rule except as provided in Rule 3.00.82(a)(2);
 - 2) Any drug dispensed in a traditional dispensing system;
 - 3) Any drugs dispensed in a customized patient medication package;
 - 4) Any drug packaged in a single dose package, a unit dose dispensing system, a unit dose package, or a unit of issue package that is not labeled in accordance with Rules 3.01.20 and 3.01.21;
 - 5) A compounded drug;
 - 6) Drugs that are adulterated or misbranded as determined by the pharmacist;
 - 7) Drugs that require refrigeration, freezing, or special storage;
 - 8) Drugs that require special registration with the manufacturer;
 - 9) Drugs that will expire prior to utilization by the consumer, based on the prescribing practitioner's directions for use;
 - 10) Dispensed drugs that are received from facilities or pharmacies located outside of Colorado; and
 - 11) Any drug that was not dispensed pursuant to an order.

3.00.85 Records of Receipt of Returned or Donated Prescriptions, Medical Devices, and Medical Supplies.

- a. The prescription drug outlet shall retain records for at least two years detailing receipt of donated or returned prescriptions that contain at least the following information:

-
- 1) Name and address of facility or donating prescription drug outlet;
 - 2) Name and address of originating prescription drug outlet;
 - 3) Prescription number or unique identifier assigned at originating prescription drug outlet;
 - 4) Name and address of each prescription drug outlet having possession of the drug, device, or supply after the originating prescription drug outlet and the dates the product was in each prescription drug outlet's possession.
 - 5) Date of return or donation;
 - 6) Name, strength, and NDC number of drug received;
 - 7) Name of medical device or medical supply received; if applicable;
 - 8) Quantity received;
 - 9) Date received;
 - 10) Drug, medical device, or medical supply expiration date;
 - 11) Receipt record must state, "Returned or Donated Prescription, Device, or Supply"
- b. Records detailing the receipt of returned or donated prescriptions, devices, and supplies, as required by Rule 3.00.84(a)(1) through (11) may be maintained electronically if 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) Have and maintain a complete on-line receipt file that is printable on the inspector's request;
 - 3) Have a "lock-out" feature that prevents editing of receipt information;
 - 4) The Board or its inspectors must be able to inspect and review all of the prescription drug receipt transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:
 - (a) Print a report of all prescription drug receipt transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours; or

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

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

3.00.86 Storage of Returned or Donated Prescription, Medical Devices/Supplies, and Establishment of Handling Fee.

- a. Returned or donated prescriptions, medical devices, and medical supplies shall be stored in a separate area from other drug stocks belonging to the pharmacy. This area shall be conspicuously labeled with a sign indicating that such area contains only returned or donated prescriptions, medical devices, or medical supplies.
- b. An entity that receives a donated medication, medical device or medical supply may charge the end user a handling fee, which shall not exceed three dollars for each complete prescription, medical device or medical supply dispensed to the end user and shall not resell the donated medication, medical device or medical supply for profit.

3.00.87 Dispensing of Returned or Donated Prescriptions, Medical Devices, or Medical Supplies.

- a. Special Conditions for Dispensing Returned or Donated Drugs:
 - 1) 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.
 - 2) 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 Rule 3.00.82((a)(2), provided that the integrity of the product and the package are maintained.
 - 3) 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 (5) 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.
 - 4) 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 (5) below. Single dose packages may not be emptied and the drugs removed and packaged.
 - 5) 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.

- 6) Prescriptions dispensed using returned or donated prescriptions shall be labeled according to section 12-280-124, C.R.S. Additionally, the label shall state, "Donated or Returned Drug."

b. Records of Dispensing

All records of dispensing shall be compliant with Rules 2.00.00, 3.00.00, and 11.00.00. These records of dispensing, including prescription orders, shall be maintained separately from dispensing records of drugs that were not donated or returned.

3.00.88 Donating Returned or Donated Prescriptions, Medical Devices, or Medical Supplies.

a. Prescription drug outlets may donate the returned or donated prescriptions, medical devices, or medical supplies to any of the following:

- 1) Nonprofit entity as defined in Rule 3.00.81(g); or
- 2) A practitioner authorized by law to dispense the drug.

b. Records of donation shall include the following:

- 1) The name of the drug, medical device, or medical supply;
- 2) The strength of the drug;
- 3) The dosage form if appropriate;
- 4) The quantity of the drug, medical device, or medical supply;
- 5) The manufacturer name and/or NDC number of the drug if labeled only with its generic name;
- 6) The date of donation;
- 7) The name and address of the donating prescription drug outlet;
- 8) The name and address and registration number of the nonprofit entity receiving the drug, medical device, or medical supply, or the name, address, and license number of the practitioner receiving the drug, medical device, or medical supply.
- 9) The name and address of the originating prescription drug outlet;
- 10) The prescription number or unique identifier assigned to the prescription at the originating prescription drug outlet.
- 11) The date the medication expires; and
- 12) The name and address of each prescription drug outlet, other than the originating prescription drug outlet, having possession of the prescription and the dates the prescription was in that prescription drug outlet's possession.

c. A copy of the donation record shall be maintained at the prescription drug outlet and a copy of the same record shall be furnished to the receiving individual or entity.

- d. Records detailing the donation of prescriptions, medical devices, and medical supplies, as required by Rules 3.00.88(b)(1) through (12) may be maintained electronically if 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) Have and maintain a complete on-line donation file that is printable on the inspector's request;
 - 3) Have a "lock-out" feature that prevents editing of donation information;
 - 4) The Board or its inspectors must be able to inspect and review all of the donation transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:
 - (a) Print a report of all donation transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours; or
 - (b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review donation 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).
 - 5) It is the responsibility of the pharmacist manager of the outlet to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the pharmacist manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.

3.00.89 Record Retention

- a. All records of receipt and dispensing shall be maintained for a period of two years from the date of receipt, or from the last dispensing transaction date. Such records shall be maintained separately from all other records of the prescription drug outlet.
- b. All records of donation shall be maintained for a period of three years from the date of donation. Such records shall be maintained separately from all other records of the prescription drug outlet.

3.00.90 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.
 - (4) No compounded or flavored prescriptions may be returned to stock.

3.00.91 Prescriptions dispensed by prescription drug outlets for delivery to consumers in other other outlet settings. When a drug has been dispensed pursuant to prescription order at a prescription drug outlet but has not been delivered to the ultimate consumer at an other outlet, the drug may be returned to stock only at the originating Prescription Drug Outlet, for subsequent redispensing provided that:

- a. The prescription drug outlet complies with Rules 3.00.90(a), (b), and (c);
- b. The storage conditions during the transport of the prescription to and from the other outlet do not in any way compromise the integrity or stability of the drug;
- c. No controlled substance prescriptions may be returned to stock; and
- d. No compounded or flavored prescription 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 pharmacy technician 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 packaged drugs shall only be distributed as provided in Rule 3.01.10(d).
- c. Any container used for packaging shall meet compendia requirements.
- d. The following prescription drug outlets may distribute packaged medications without limitation to prescription drug outlets and other outlets under common ownership:
 1. Prescription drug outlets owned and operated by a hospital that is accredited by the joint commission on accreditation of healthcare organizations or a successor organization pursuant to 12-280-120(15)(b), C.R.S;
 2. Prescription drug outlets operated by a health maintenance organization as defined in section 10-16-102, C.R.S.; and
 3. The Colorado Department of Corrections.

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 Rule. Any packaged unit dose, single dose or unit of issue container for which return for restocking and redispensing, pursuant to Rule 3.00.80, is anticipated, shall be labeled in accordance with this Rule. Additionally, any packaged container from which subsequent dispensing may occur, shall be labeled in accordance with this Rule. 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 (d), (e), (f), (g), and (h) of this Rule may be omitted from the labeling and maintained in such record. An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot packaged. In another outlet the record shall be signed by the person specified in the Board approved protocol. The record shall be retained for two years from the date of packaging unless otherwise required by law or rule.
- 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. Sterile packaged product beyond-use dating shall comply with Rule 3.01.34(h)(3));
- d. The identity of the manufacturer or distributor;
- e. The manufacturer's or distributor's lot number;
- f. The manufacturer's or distributor's expiration date;
- g. The date the product was packaged;

- h. The identity of the pharmacist responsible for packaging in a prescription drug outlet, or, in the case of an other outlet, the identity of the non-pharmacist permitted to do so pursuant to protocols approved by the Board.
- i. The name and address of the packaging pharmacy if the drug is distributed by a prescription drug outlet owned and operated by a hospital that is accredited by the Joint Commission of Accreditation of Healthcare Organizations or a successor organization or by a prescription drug outlet operated by a health maintenance organization as defined in section 10-16-102, C.R.S. Such drugs may only be distributed to prescription drug outlets under common ownership.

3.01.21 If the unit dose package or unit of issue package is obtained from the manufacturer or distributor and complies with applicable federal requirements, such package may be dispensed without additional labeling as required in Rule 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. 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. The record shall be retained for two years from the date of packaging, unless otherwise required by law or rule.
 - 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 individual responsible for packaging, or in the case as provided in this Rule 3.01.22(f), the identity of the persons responsible for packaging;
 - 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.
- f. A pharmacy technician may replenish automated cassettes without the need for a pharmacist's verification as long as the pharmacy technician uses bar code technology that checks the accuracy of the medication or a second pharmacy technician performs the verification.

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 Rule 3.01.22 c (1-8) shall be entered into the system at the time of the transaction.
- b. Every twenty-four hours the system must produce a hard-copy document that, for the purposes of these Rules, 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 twenty-four hours and shall contain all information required by this Rule. 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 Rule 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 Rule 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 seventy-two 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 Rules.
- e. Whether the prescription drug outlet elects to comply with Rule 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, whichever is sooner;
 3. The identity of the manufacturer or distributor;
 4. The manufacturer's or distributor's lot number(s);
 5. The manufacturer's or distributor's expiration date;
 6. The date the product was packaged;
 7. The identity of the pharmacist responsible for packaging in a prescription drug outlet, or, in the case of an other outlet, the identity of the non-pharmacist permitted to do so pursuant to protocols approved by the Board;

3.01.25 Maintenance and cleaning of automated cassettes

- a. The outlet must maintain, on-site and available for inspection, the manufacturer's guidelines for maintenance and cleaning of the cassettes.
- b. The maintenance and cleaning schedule recommended by the manufacturer shall be adhered to and records of performed maintenance shall be available for inspection for a period of at least two years.
- c. If the outlet changes the drug used in a cassette, the cassette must be thoroughly cleaned per manufacturer's recommendations prior to using the cassette for a different drug.

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

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

3.03.00 Customized Patient Medication Packages (Med Paks).

3.03.10 When a unit dose, single dose, unit of issue or customized patient medication package is dispensed pursuant to an order, the prescription shall comply with all requirements of section 12-280-124(2), C.R.S. 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 each of the orders detailing 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 shall not exceed 90 days from the date of preparation; and
- (8) The name, address, and telephone number of the dispenser.

b. Record Keeping.

- (1) Patient name and address;
- (2) The serial number of the 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; and
- (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.
- e. The med pak is assigned a new serial number.
- f. The labeling of the med pak is modified to comply with Rule 3.03.10(a). The expiration date affixed to the label prior to modification must be retained.
- g. Records are maintained for the modified med pak which comply with Rule 3.03.10(b).

3.04.00 Colorado Cancer Drug Repository Program. [Repealed]

3.05.00 Pharmacist Prescribing and Dispensing Over-the-Counter Medications

3.05.10 Pharmacists, pursuant to 12-280-103(34), 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 12-280-103(31)(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 12-280-124, 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. The Colorado Department of Health Care Policy and Financing sets forth the requirements in 10 CCR 2505-10, 8.800 of June 30, 2018. This incorporation does not include later revisions of the rule. Copies of the rule are available for public inspection during regular business hours at 1570 Grant Street, Denver, Colorado, 80203. The rules are readily available in written or electronic form at <http://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=7643&fileName=10%20CCR%202505-10%208.800>. The rules are available for a reasonable fee from the Department of Regulatory Agencies, Division of Professions and Occupations.

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.

4.00.00 LICENSING.

4.00.10 Definitions

- a. "Academic examination" is the North American Pharmacist Licensure Examination.
- b. "Board-approved foreign pharmacy graduate certification" means the Foreign Pharmacy Graduate Equivalency Certification.
- c. "Board-approved jurisprudence examination" means the Colorado-specific Multistate Pharmacy Jurisprudence Examination.
- d. "Board-approved school or college of pharmacy" is a professional degree program of a school or college of pharmacy that has an accredited or preaccredited status from the Accreditation Council for Pharmacy Education ("ACPE").
- e. "Board-designated clearinghouse for license transfer" means the National Association of Boards of Pharmacy Clearinghouse operated by the National Association of Boards of Pharmacy.
- f. "Disenrollment" means the current status of a pharmacy student who no longer possesses the right or capacity to complete the curriculum in the allotted time as set forth in the policies of the corresponding Board-approved school or college of pharmacy.
- g. "Enrollment" means the current status of a pharmacy student who possesses the right or capacity to complete the curriculum in the allotted time as set forth in the policies of the corresponding Board-approved school or college of pharmacy.
- h. "Intern" means a person who is:
 - (1) Enrolled in a professional degree program of a Board-approved school or college of pharmacy, licensed by the Board to engage in the practice of pharmacy, and satisfactorily progressing toward meeting the requirements for licensure as a pharmacist;
 - (2) A graduate of a Board-approved school or college of pharmacy or a graduate who has established education equivalency by obtaining a Board-approved foreign pharmacy graduate certification and who is currently licensed by the Board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist; or

- (3) A qualified pharmacist applicant awaiting examination for licensure as a pharmacist or meeting Board requirements for pharmacist licensure.
- i. "License transfer or endorsement" is the licensing of an individual who is licensed as a pharmacist by examination in another state and whose license in that state is in good standing.
- j. For the purposes of this Rule 4.00.00, "manufacturer" means a manufacturer of prescription drugs which is registered by the Board.
- k. "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.
- l. "Regulated individual" means any of the following individuals holding an active, unrestricted license, registration, or certification from the Colorado Department of Regulatory Agencies:
 - (1) Clinical Social Worker;
 - (2) Dentist;
 - (3) Occupational Therapist;
 - (4) Optometrist;
 - (5) Physical Therapist;
 - (6) Physician;
 - (7) Physician Assistant;
 - (8) Podiatrist;
 - (9) Psychologist;
 - (10) Registered Nurse or Advanced Practice Nurse;
 - (11) Respiratory Therapist; and
 - (12) Veterinarian.
- m. "Score transfer" is the transfer of the academic examination score to Colorado by participation in the NAPLEX Score Transfer Program operated by the National Association of Boards of Pharmacy.

4.00.20 Requirements for Intern Licensure include the following;

- a) Submission of a completed application form provided by the Division of Professions and Occupations with the appropriate fee.
- b) Submission of one of the following:

- 1) Proof of enrollment in a Board-approved school or college of pharmacy. A person on suspension from a Board-approved school or college of pharmacy may not be licensed as an intern. A person in good standing with a Board-approved school or college of pharmacy may be licensed as an intern.
- 2) If a graduate of a foreign school or college of pharmacy, a Foreign Pharmacy Graduate Equivalency Certification;
- 3) Proof of graduation within the prior two years from a Board-approved school or college of pharmacy. If the applicant ceased to be enrolled in a Board-approved school or college of pharmacy more than two years prior to application, the applicant shall include an explanation of "good cause" for licensure which the Board or its designee shall review and act on in the normal course of business.
- 4) If a pharmacist in another state awaiting pharmacist licensure in Colorado, verification of an active, unrestricted license in another state.

4.00.25 Requirement for Intern Reporting. An actively licensed intern shall report to the Board, in writing, within thirty days of meeting the definition of "Disenrollment" as defined in Rule 4.00.10(f) from a Board-approved school or college of pharmacy.

4.00.30 Requirements for Pharmacist License by Exam or Score Transfer include the following:

- a. Submission of a completed application form provided by the Division of Professions and Occupation with the appropriate fee.
- b. Submission of a transcript and proof of graduation from a Board-approved school or college of pharmacy or a Foreign Pharmacy Graduate Equivalency Certification.
- c. Successful passage of the academic examination and Board-approved jurisprudence examination. The passing scores for these examinations are set by the examining entity. If an applicant passes only one of the required examinations, the applicant shall be required to repeat the failed examination. If, within the previous twenty-four months, the applicant has not passed both required examinations, he or she shall be required to also repeat the previously passed examination. Score transfer applicants shall complete licensure within one year from the date their scores are received by the Division of Professions and Occupations.
- d. Proof of completion of 1500 intern hours completed no more than five years after graduation from a Board-approved school or college of pharmacy. If a graduate of an unapproved school or college of pharmacy, receipt of the Foreign Pharmacy Graduate Equivalency Certification. Intern hours must be obtained under one or more of the following conditions:
 - (1) Engaged in the practice of pharmacy under the direct supervision of a pharmacist.
 - (2) Directly supervised by a manufacturer as part of the curriculum of an approved school or college of pharmacy.
 - (3) Directly supervised by a regulated individual as part of the curriculum of an approved school or college of pharmacy. The scope of practice of the regulated individual must overlap with that of a pharmacist for the course of the hours supervised.

- (4) One year of practice of pharmacy as a licensed pharmacist in another state may be accepted by the Board in lieu of the 1500 hours if the applicant has completed this year of pharmacy practice prior to taking the examination.
- e. Education, training, or service gained in military services or licensure, certification, registration, or enrolled in good standing through the federal government as outlined in section 12-20-202, C.R.S., to be accepted and applied towards receiving a license, must be substantially equivalent, as determined by the Board, to the qualifications otherwise applicable at the time of receipt of application. It is the applicant's responsibility to provide timely and complete evidence for review and consideration. Satisfactory evidence of such education, training, or service will be assessed on a case by case basis.

4.00.40 Requirements for License Transfer or Endorsement are as follows:

- a. Submission of a completed application and fee to the Board designated clearinghouse for license transfer.
- b. Submission of a completed application form provided by the Division of Professions and Occupations with the appropriate fee.
- c. Successful passage of the Board-approved jurisprudence examination. The passing score is set by the examining entity.
- d. Applicants for license transfer must have been licensed as a pharmacist for at least one year in another state or have served an Internship meeting the Colorado requirements at the time of original licensure.
- e. A person duly licensed, certified, registered, or enrolled through the federal government under the conditions set forth in section 12-20-202, C.R.S., to practice pharmacy or who possesses the education, training, or service gained in military services pursuant to section 12-20-202, C.R.S., is upon application to the Board, eligible for licensure.
- f. An applicant for license transfer shall apply for license transfer using a license issued by examination in another state. Such license shall be active, current, and in good standing. If the applicant holds pharmacist licenses in multiple states, all licenses must be in good standing. For the purposes of these Rules, "good standing" means that the applicant is not currently subject to active disciplinary actions in any state.

4.03.00 Reinstatement or Reactivation of Pharmacist License.

- a. If the license has been inactive or expired for over twenty-four months, a person wishing to reinstate or reactivate such license shall do the following:
 - (1) Submit the appropriate application with the required fee;
 - (2) Submit one hour of continuing education for each month such license was inactive or expired. Twenty-four of these hours shall have been completed in the twenty-four months prior to application for reinstatement or reactivation; and
 - (3) Take and pass the approved jurisprudence examination. The passing score shall be set by the examining entity.
- b. If the license has been expired or inactive for less than twenty-four months, a person wishing to reinstate or reactivate such license shall do the following:

- (1) Submit the appropriate application with the required fee; and
- (2) Submit twenty-four hours of continuing education completed within the twenty-four months prior to application.

4.05.00 License Changes.

- a. Name change. A licensee shall report a name change and provide appropriate supporting documentation within thirty days of such change. If the licensee wishes to obtain a new wall license with the new name, the licensee shall pay the requisite fee.
- b. Change of residential and electronic mail address. All pharmacists and interns shall notify the Board in writing within thirty days of any change of residential or electronic mail 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, pharmacy intern, pharmacy technician, pharmacy clerk, store manager, or assistant store manager shall at all times while on duty within a prescription drug outlet wear a badge which is visible to the patient and which shall state at least the title accurately reflecting a person's role in the outlet such as Pharmacist, Pharmacy Intern, Pharmacy Technician, Pharmacy Clerk, Store Manager, or Assistant Store Manager.

5.00.00 OUTLETS.

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

- a. Compounding / Dispensing Area: means any area in a prescription drug outlet where "compounding / dispensing" is performed.
- b. In-State Prescription Drug Outlet: means any prescription drug outlet located within Colorado that is registered pursuant to Title 12, Article 280, C.R.S., where prescriptions are compounded and dispensed.
- c. Non-Resident 503 Outsourcing Facility: means a facility that is registered by the Federal Food and Drug Administration, that is located outside the state, and that distributes compounded drugs into the state without a prescription order.
- d. Non-Resident Prescription Drug Outlet: means any pharmacy outlet located outside this state that is registered pursuant to Title 12, Article 280, C.R.S., which ships, mails, or delivers, in any manner, drugs or devices into this state pursuant to a prescription order.
- e. Risk-Base Assessment: means, pursuant to section 12-280-108(1)(a)(II), C.R.S., to inspect a non-resident prescription drug outlet, a non-resident 503B outsourcing facility, or an out-of-state prescription drug wholesaler when the Board determines, based on a complaint, that there may be an imminent threat to the health, safety and welfare of Colorado consumers and that such an inspection is imperatively necessary to preserve health, safety and welfare of Colorado consumers.
- f. Third-Party Logistics Provider: means a person that contracts with a manufacturer to provide or coordinate warehousing, distribution, or other services on behalf of a manufacturer but does not take title to a prescription drug or have general responsibility to direct the prescription drug's sale or distribution.

- g. “Automated Pharmacy Dispensing System” or “System” means a mechanical system that dispenses prescription drugs to a person interacting with a remote pharmacist and maintains related transaction information.
 - (1) An “Automated Pharmacy Dispensing System” may only be operated under a Pharmacy Drug Outlet license type.
 - (2) Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist, or a pharmacy technician (provisional and non-provisional) or intern under the supervision of a pharmacist.

5.00.10 Registration. The applicant for registration shall obtain the appropriate form as approved by the Board to register an outlet. In the case of an application for a new in-state or non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider, for a transfer of ownership of an in-state or non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider, or for the relocation of an in-state or non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider, the applicant shall submit such additional documentation as the Board may require.

5.00.15 Registration for nonresident prescription drug outlets. An applicant for a new nonresident prescription drug outlet registration shall submit the following:

- a. The current application with required fee;
- b. A verification of the current pharmacy license or registration issued by the applicant’s resident state board of pharmacy;
- c. A copy of the most recent report detailing an inspection of the nonresident prescription drug outlet by either its resident state board of pharmacy or the National Association of Boards of Pharmacy’s Verified Pharmacy Program dated within the previous two years of submission of the application; and
- d. An affidavit attesting that the nonresident prescription drug outlet shall not ship compounded or other prescription drugs into the State of Colorado without a prescription order for a specific patient, except as provided pursuant to Rule 21.00.20.

5.00.17 Non-Resident 503B Outsourcing Facility. A nonresident 503B outsourcing facility shall submit the following to the Board with the application:

- a. Proof that the facility is actively registered with the Federal Food and Drug Administration as a 503B outsourcing facility and is actively licensed, permitted, or registered in the state in which it is a resident;
- b. The location, names, and titles of all principle entity officers and the name of the pharmacist in charge of the operations of the facility;
- c. Verification that the facility complies with all lawful directions and requests for information from the Federal Food and Drug Administration and from the regulatory or licensing agency of the state in which it is licensed, permitted, or registered, as well as all requests for information made by the Board pursuant to this section; and
- d. A copy of the most recent inspection report resulting from an inspection by the Federal Food and Drug Administration.

5.00.19 Third-Party Logistics Provider. A third-party logistics provider shall submit the following to the Board with the application:

- a. Proof, if available, that the facility is actively registered with the Federal Food and Drug Administration as third-party logistics provider;
- b. The location, names, and titles of all principle entity officers; and
- c. Verification that the facility complies with all lawful directions and requests for information from the Federal Food and Drug Administration as well as all requests for information made by the Board pursuant to this section.

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

5.00.21 Automated Pharmacy Dispensing System. Requirements for Registration. Eligibility requirements for an Automated Pharmacy Dispensing System application include the following:

- a. Automated Pharmacy Dispensing Systems do not include those that do not involve direct patient interaction and are for internal operations use only.
- b. 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 patients receiving prescriptions from the Automated Pharmacy Dispensing System;
- c. The submission of a separate application by the managing prescription drug outlet on behalf of the Automated Pharmacy Dispensing System for an Automated Pharmacy Dispensing System registration, on a form provided by the Division of Professions and Occupations. The managing prescription drug outlet shall submit an application for each individual Automated Pharmacy Dispensing System to which the managing prescription drug outlet will provide stock drugs;
- d. A Drug Enforcement Administration registration specifically assigned to the Automated Pharmacy Dispensing System if the managing prescription drug outlet provides stock controlled substances to the Automated Pharmacy Dispensing System;
- e. 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 Automated Pharmacy Dispensing System; and
- f. A secure Automated Pharmacy Dispensing System that prevents the diversion of drugs and that limits the access to drugs within the Automated Pharmacy Dispensing System only to those persons whom have been given permission to access the Automated Pharmacy Dispensing System;
- g. The necessary fee;
- h. The APDS shall be located in the state of Colorado and a pharmacist providing any clinical services, including initial and final interpretation, must be licensed in the state of Colorado.
- i. Automated pharmacy dispensing systems may be stocked or loaded by a pharmacist or a pharmacy technician (provisional and non-provisional) or intern under the supervision of a pharmacist.

5.00.30 No two registered in-state or non-resident prescription drug outlets may occupy the same physical space. If there are two (or more) registrants co-located within the same building or at the same address, each must have its own area, separated by floor to ceiling walls, and separate entrances.

5.00.40 Transfer of Ownership. Application to transfer registration of an in-state or non-resident prescription drug outlet or a non-resident 503B outsourcing facility or third-party logistics provider shall be submitted to the Board within thirty (30) days of the transfer of ownership. A transfer of ownership shall be deemed to have occurred:

- a. In the event the in-state or non-resident prescription drug outlet or a non-resident 503B outsourcing facility or third-party logistics provider is owned by a corporation, upon sale or transfer of twenty percent or more of the shares of said corporation to a single individual or entity.
- b. In the event the in-state or non-resident prescription drug outlet or a non-resident 503B outsourcing facility or third-party logistics provider is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.
- c. In the event the in-state or non-resident prescription drug outlet or a non-resident 503B outsourcing facility or third-party logistics provider is owned by a limited liability company (LLC), upon sale or transfer of twenty percent or more of the membership interests.
- d. Upon incorporation of an existing in-state or non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider.

5.00.50 Relocation.

- a. In the event of a relocation of an in-state or non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider, the outlet shall submit an application provided by the board along with the prescribed fee no more than thirty (30) days prior to the effective date of relocation.
- b. The registration of a non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider shall become void and shall be cancelled if the non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider relocates to a state other than that which appears on its registration. In the event the non-resident prescription drug outlet or non-resident 503B outsourcing facility or third-party logistics provider wishes to continue conducting business in Colorado, it must apply for and receive a new Colorado registration prior to conducting business in Colorado.

5.00.55 Reinstatement of an In-State or Non-Resident Prescription Drug Outlet Registration.

- a. In-state Prescription Drug Outlet. If a registration has expired, a facility seeking to reinstate such registration shall submit the following:
 - (1) The current reinstatement application with the required fee;
 - (2) If the owner of the in-state prescription drug outlet is a corporation, submit either a copy of the articles of incorporation as they were filed with the Colorado Secretary of State or a Certificate of Good Standing issued by the Colorado Secretary of State;
 - (3) A letter stating whether the corporation is public or private as follows:

- (A) If the corporation is a public corporation, submit a list of all stockholders owning five percent or more of the stock; or
 - (B) If the corporation is a private corporation, submit a list of all stockholders;
- (4) An accurate drawn-to-scale floor plan of the prescription drug outlet's compounding / dispensing area detailing all counters, bays, sinks, refrigerators and, if applicable, sterile and non-sterile compounding hoods; and
- (5) A completed, dated and signed minimum equipment self-inspection form as provided with the reinstatement application.
- b. Non-resident Prescription Drug Outlet or non-resident 503B outsourcing facility or third-party logistics provider. If a registration has expired, a facility seeking to reinstate such registration shall submit the following:
 - (1) The current reinstatement application with the required fee;
 - (2) A verification of the current pharmacy license, registration, or permit issued by the resident state board of pharmacy for the non-resident pharmacy or 503B outsourcing facility, and a verification of the current license or registration issued by the Federal Food and Drug Administration for a non-resident 503B outsourcing facility or third-party logistics provider;
 - (3) If the registration has expired for a non-resident pharmacy for more than two years, a copy of the most recent report detailing an inspection of the non-resident prescription drug outlet by its resident state board of pharmacy dated within five years of submission of the reinstatement application.

5.00.60 Closure.

- a. Closure shall mean the permanent cessation of the practice of pharmacy in any in state or non-resident prescription drug outlet or the permanent cessation of conducting business in Colorado for a non-resident 503B outsourcing facility or third-party logistics provider. For in-state prescription drug outlets, closure shall also be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in Rule 5.01.40(a).
- b. Upon the closure of any in-state or non-resident prescription drug outlet, it shall be the responsibility of the last pharmacist manager of record to remove the prescriptions and/or chart orders to another prescription drug outlet where patrons and/or practitioners are afforded reasonable access to a pharmacist's interpretation of such orders. Such relocation of records shall be made within seventy-two hours after closure. The pharmacist manager shall submit a notice, on a form and manner approved by the Board, detailing the closure of the prescription drug outlet or nonresident prescription drug outlet within seventy-two hours after closure. 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. A non-resident 503B outsourcing facility or third-party logistics provider shall inform the Board, in writing, within seventy-two hours after closure.
- c. The Board on request shall provide the owner of any prescription drug outlet an instruction sheet applicable to the transaction prior to closure, or conducting bankruptcy proceedings, or transferring or selling the prescription drug inventory.

- d. The preceding subsections under 5.00.60 shall not apply if a public health order is in effect and consequently and temporarily impacts operating hours.

5.00.70 Change in Pharmacist manager.

- a. An in-state and non-resident prescription drug outlet shall be under the direct charge of a pharmacist manager. A proprietor who is not a pharmacist shall comply with this requirement and shall provide a manager who is a pharmacist.
- b. The registration of any in-state and non-resident prescription drug outlet shall become void if the pharmacist manager in whose name the registration was issued ceases to be engaged as the manager, and the owner shall close the outlet unless such owner has employed a pharmacist manager and, within thirty days after termination of the former manager's employment, has made application to transfer the registration to the new pharmacist manager and has paid the transfer fee therefor.

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

5.01.00 Prescription Drug Outlets (In-State).

5.01.10 Controlled Substance Inventory.

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

5.01.20 Compounding/Dispensing Area (In-State)

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

5.01.31 Within every prescription drug outlet as defined in section 12-280-103(43), C.R.S., 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 twelve continuous square feet of free and clear counter space, and a minimum of six 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 thirty inches in width;

- (2) The free floor space between shelving rows shall be not less than twenty-four 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 twenty-four inches of free floor space between shelving rows; and
 - (2) At least thirty 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.) or in accordance with the corresponding drug manufacturer's directions. 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.) or in accordance with the corresponding drug manufacturer's directions. 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.

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- I. 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 Title 12, Article 280, C.R.S.; the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act;
 - (2) Title 18, Article 18, C.R.S., 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 hazardous 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, 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 Rule 1.00.16, and the federal Health Insurance Portability and Accountability Act of 1996.

5.01.33 The use of any tobacco product in any compounding/dispensing area is hereby prohibited. However, this Rule 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. 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 thirty-two hours per week on an updated permanent basis (beyond a 2 week temporary basis), 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 thirty days prior to the date on which the hours of operation will be less than thirty-two hours per week.
- c. In the event a pharmacy is not able to remain open during the posted hours of operation on a temporary basis, then it must notify the public by posting a sign in front of the closed pharmacy notifying the public of the temporary closure and contact information of the nearest closest pharmacy, their address, and phone number in an effort to provide continuity of care. Additionally, closure must be noted on each telephone greeting and pharmacy operated internet application as soon as possible, with information on hours, prescription pick-ups, and alternative options for the public to get their medication.

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 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 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 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 two 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 sections 12-280-120(4) and 12-280-123(1), C.R.S., and Rule 11.05.20.

6.00.00 [Repealed eff. 05/15/2020]

7.00.00 PHARMACIST MANAGER RESPONSIBILITIES.

7.00.10 Reporting Violations. The pharmacist manager of a prescription drug outlet shall report to the Board, in writing, within the timelines set forth below:

- a. Diversion, theft or significant unaccountable loss of prescription drugs or controlled substances from the pharmacy, hospital or health maintenance organization (as defined in section 10-16-102, C.R.S.) within one business day of a substantiated loss. When a Drug Enforcement Administration (DEA) Form 106 is submitted to the DEA in instances involving controlled substances, a copy of the completed DEA Form 106 along with a detailed written explanation shall be submitted to the Board within one business day of signing the form. When determining whether an unaccountable loss is significant, the pharmacist manager shall consider, among others factors, the following:
 - (1) The actual quantity of drug lost in relation to the type of business;

- (2) The specific drug lost;
 - (3) Whether the loss of the drug can be associated with access to those drugs by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drug;
 - (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
 - (5) Whether the specific drug is a likely candidate for diversion; and
 - (6) Local trends and other indicators of the diversion potential of the missing drug.
- b. Security breaches within the pharmacy or pharmacy area of the establishment within ten days of discovery.
 - c. Any pharmacist working in the pharmacy who is impaired due to the use of alcohol or drugs, or a pharmacist with a mental or physical impairment which affects his ability to perform his job competently. In such instance the report shall be submitted to the Board immediately upon discovery.
 - d. Significant errors related to the practice of pharmacy, including those related to compounding, such as those that result in serious personal injury or death of a patient. In such instance the report shall be submitted to the Board immediately upon discovery.

7.00.20 Administrative Reporting Responsibilities:

- a. A pharmacist manager shall immediately notify the Board in writing of the date he ceases to be the pharmacist manager of a prescription drug outlet.
- b. Upon the change of pharmacist manager of a prescription drug outlet, the new pharmacist manager or the new pharmacist manager's designee shall take an inventory of all controlled substances within seventy-two hours. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.
- c. Upon the transfer of ownership of a prescription drug outlet, the pharmacist manager or the pharmacist manager's designee shall take an inventory of all controlled substances. The inventory shall be taken either as of the opening or as of the close of business activity on the inventory date and such time and date taken shall be entered on the inventory record.
- d. The pharmacist manager shall determine or approve procedures for prescriptions delivered or temporarily stored outside the confines of a compounding/dispensing area at the request of a patient or an agent of the patient. This procedure shall include the storage of, security of, the access to, the confidentiality of, and the counseling regarding, prescriptions and necessary record keeping.
- e. Upon the closure of a 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 rule. 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 Rules.
- h. It is the responsibility of the pharmacist manager to maintain records as required by Rule 11.00.00.
- i. It is the responsibility of the pharmacist manager to maintain records of initial interpretation and final evaluation as required by Rule 3.00.51(a) and (b).
- j. It is the responsibility of the pharmacist manager to maintain and to assure the outlet's compliance with a policy and procedure manual, where applicable, encompassing all aspects of non-sterile and sterile compounding as required by Rules 21.10.10 and 21.20.30, respectively. The annual review of such manual or manuals shall be signed and dated by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within thirty days of becoming the pharmacist manager.

7.00.30 Compliance of Outlet:

- a. The manager of a prescription drug outlet is responsible for the operation of the outlet in compliance with all state and federal laws, rules, and regulations.
- b. Except as provided in sections 12-280-103(54)(b)(III) and 25.5-2.5-201 through 25.5-2.5-208, C.R.S., the pharmacist manager is responsible for ensuring that all prescription drugs and controlled substances are procured by the outlet from an entity or person registered by the Board. 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 section 12-280-131(2), C.R.S.

8.00.00 ADVERTISING.

- 8.00.10 Labels. At least one address shall appear on a prescription label and that shall include the address of the prescription drug outlet from which the prescription was dispensed. In the case of a central fill prescription processing contract, the label shall contain at least the name and address of the originating and/or fulfillment pharmacy.
- 8.00.20 Prescription Order Forms. No prescription drug outlet shall provide any practitioner with prescription order forms that refer to a pharmacist or prescription drug outlet.
- 8.00.30 Multiple Names. A prescription drug outlet shall only use, operate or advertise under the name that appears on the current registration issued by the Board.
- 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. A licensee or registrant shall notify The Board in writing within seventy-two hours of the licensee or registrant receiving service of process or knowledge by other means of any legal proceedings in Colorado or anywhere wherein it is alleged that the licensee or registrant has violated any law or rule pertaining to drugs or devices. This includes civil malpractice cases.
 - 1. The notice to the Board shall include the following information:
 - (a) The court;
 - (b) The jurisdiction;
 - (c) The case name;
 - (d) The case number; and
 - (e) A description of the matter and a copy of the indictment or charges.
 - 2. The licensee or registrant shall notify the Board in writing within thirty days of the disposition of such proceeding.
- b. All licensees or registrants shall notify the Board in writing within thirty days of any disciplinary action against them in another state. Such notification shall include the following:
 - 1. The state;
 - 2. The jurisdiction;
 - 3. The case name;
 - 4. The case number;
 - 5. A description of the matter and a copy of the indictment or charges;
 - 6. A copy of the discipline; and
 - 7. Proof of completion of any requirements set forth in the order, if applicable.
- c. All licensees or registrants shall notify the Board in writing of any criminal conviction or deferred judgment against them (including, but not limited to, "driving under the influence" and "driving while ability impaired"), and petty offenses within thirty days after such conviction or judgment.
 - 1. For purposes of this Rule, a "conviction" includes:
 - (a) A guilty verdict;
 - (b) A plea of guilty accepted by the court;
 - (c) A plea of nolo contendere (no contest) accepted by the court; or

- (d) A deferred judgment or sentence.
- 2. The notice to the Board shall include the following information:
 - (a) The court;
 - (b) The jurisdiction;
 - (c) The case name;
 - (d) The case number;
 - (e) A description of the matter and a copy of the indictment or charges;
 - (f) A copy of the plea agreement or verdict; and
 - (g) Proof of completion of court ordered requirements, if applicable.
- d. The registrant or licensee notifying the Board may submit a written statement with any notice required under this Rule to be included in the registrant or licensee records.
- e. Each insurance company licensed to do business in Colorado and engaged in the writing of malpractice insurance for licensed pharmacists and each pharmacy that self-insures shall send to the Board, information relating to each malpractice claim against a licensed pharmacist which is settled or in which judgment is rendered against the insured. Such information shall be provided to the Board within 30 days of the settlement or judgment.

10.00.00 EMERGENCY KITS.

10.00.05 Definitions.

- a. "Emergency kit" or "kit" means a tamper-evident sealed and secured container or secured electronic system containing drugs which are used for either immediate administration to patients of facilities delineated in 10.00.10 or in an emergency situation or as a starter dose.
- b. "Starter dose" means a dose of medication contained in an emergency kit for the purpose of starting the initial therapy for a patient residing in a facility delineated in Rule 10.00.10.

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

- a. Only one prescription drug outlet or hospital other outlet may provide a kit to any of the above facilities. Multiple pharmacies or hospital other outlets may not supply emergency kits to the same facility.
- b. The pharmacist manager of the prescription drug outlet supplying the kit or the consultant pharmacist of the hospital other outlet supplying the kit shall be responsible for the accurate stocking or restocking of the kit. He/she may delegate this function to non-pharmacist personnel, but the pharmacist manager or other outlet consultant pharmacist assumes responsibility for the accuracy of the contents of the kit.

10.00.20 Categories and Limits

- a. For Long-Term Care Facilities, Acute Treatment Units, and Inpatient Hospices, the medical director of the facility, or equivalent, and the consulting pharmacist shall determine the specific drugs to be kept in the kit. The number of drugs allowed in the kit shall be limited to sixty. Of the sixty, twelve may be controlled substances. The kit may contain no more than thirty doses of any separate drug dosage form or strength for each drug. The container size for each drug shall be limited to unit dose or unit of issue packaging.
- b. In the case of a Certified Home Health Agency or an Outpatient Hospice, the director of nursing of the Certified Home Health Agency or of the Licensed Hospice, and a pharmacist employed and designated by the prescription drug outlet or hospital other outlet providing the kit shall determine the specific drugs to be kept in the kit. A Certified Home Health Agency or Outpatient Hospice may not have oral dosage forms or controlled substances in the kit. The container size for each injectable drug shall be limited to unit dose or unit of issue packaging. The number of drugs allowed in the kit shall be limited to sixty. The kit may contain only thirty doses of any separate drug dosage form or strength for each drug.

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

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

- a. Name, address and telephone number of the prescription drug outlet or hospital other outlet providing the contents of the kit;
- b. The date of sealing of the kit;
- c. A suitable expiration date which shall be the earliest expiration date of any drug in the kit, but in no event shall it be more than one year from the date of sealing; and
- d. In the case of a Long-Term Care Facility, Acute Treatment Unit or Inpatient Hospice, the name of the consulting pharmacist, or, in the case of a Certified Home Health Agency or an Outpatient Hospice, the name of the designated pharmacist.

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

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

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

10.00.60 Inspection. A pharmacist employed by the prescription drug outlet or hospital other outlet providing the kit or that pharmacist's designee shall inspect and inventory the contents of the kit at least annually and within seventy-two hours after being notified that the kit has been accessed. An off-site review is acceptable, if the kit is an electronic system and meets the following requirements:

- a. chain of custody report which includes the nurses name, patient name, medication, and quantity removed;
- b. has the ability to show discrepancy in count; and
- c. has secured access to medications, unable to access medications without approved request, and only able to access the medication that is requested.

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

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

- a. The name and address of the Acute Treatment Unit, Long-Term Care Facility, Certified Home Health Agency, or Hospice;
- b. The name and strength of the drug; and
- c. The container size and the quantity initially placed in the kit.

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

- a. Date and quantity administered;
- b. Names of both the patient and practitioner;
- c. Date the drug was replaced in the kit;
- d. The quantity of the drug replaced, which shall not exceed the quantity administered or removed for administration; and
- e. The prescription order number assigned.

10.00.80 Use. The drugs shall only be administered to patients of the Acute Treatment Unit, Long-Term Care Facility, Certified Home Health Care Agency, or Hospice pursuant to the order of a practitioner.

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

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 Rules, 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 Rules 11.08.00 and 11.09.00.
- b. The following records shall be made available within forty-eight 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", or is owned and operated by a health maintenance organization (as defined in section 10-16-102, C.R.S), or the veterinary hospital owned and operated by Colorado State University or its successor organization, 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, electronic 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 twenty-four hours per day, the inventory shall specify the time the inventory was conducted.
- 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), or the veterinary hospital owned and operated by Colorado State University or its successor organization, the inventory may be taken over 72 hours if:
 - (1) Inventory is secured in automated dispensing machines
 - (2) Inventory is counted with a witness
 - (3) The date, time and users performing the count are electronically recorded and reported separately on the inventory for each medication storage bin
- e. 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.
- f. 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.
- g. 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.
 - h. 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.
 - i. All controlled substance inventories shall be retained at the prescription drug outlet for at least two years from the date of such inventory.
- 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.
 - 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 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.
- 11.04.00 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, 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 controlled 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 Rule 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 section 12-280-134(1)(a), C.R.S., Rules 11.01.00 and 11.02.00(a)(3) and (4), and Title 21 CFR 1304.04. 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 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 chart orders for 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.

11.04.20 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 Rule 11.04.20(i).
- b. Every twenty-four hours, except as provided in Rule 11.04.30, the system must produce a hard-copy document which, for the purposes of these Rules, shall be known as the "daily printout". It shall consist of a single, uniform, complete document, except as otherwise permitted in this Rule. The daily printout shall list, separately, each prescription fulfillment or LTCF chart order transaction for the previous twenty-four hours and shall contain all information required by this Rule. Daily printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages which are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable and available.
- c. The daily printout shall contain all of the following information for each prescription fulfillment or LTCF chart order transaction and shall differentiate between new and refill transactions. As an alternative, new and refill transactions may be separated into two separate uniform and complete documents which contain the following:
 - (1) The serial number;

- (2) The name of the patient;
 - (3) The name of the practitioner;
 - (4) For each controlled substance dispenses, the practitioner's Drug Enforcement Administration registration number;
 - (5) The date of issue by the practitioner, the date dispensed shall be presumed to be the date of issue.
 - (6) The total number of refills authorized;
 - (7) Date dispensed;
 - (8) The name and strength of the drug dispensed;
 - (9) The quantity of the drug dispensed;
 - (10) In the case of a refill, the total number of refills dispensed to date.
- d. Records of prescription or LTCF chart order transactions involving controlled substances shall be identifiable from those involving non-controlled substances. Alternatively a separate complete printout listing only controlled substance transactions may be produced.
- e. The daily printout shall be available for inspection by the Board within seventy-two hours from the most recent date recorded on the printout.
- f. Prescription or LTCF chart order refill transactions must be uniformly recorded on the original prescription or LTCF chart order or on the daily printout. In the event of a discrepancy between the entry on the order and the entry on the daily printout, the information recorded on the daily printout shall be deemed to be correct.
- g. Documentation of the fact that the refill information entered into the automated data processing system each time a pharmacist refills an original prescription or LTCF chart order for a schedule III, IV, or V controlled substance is correct must be provided by the pharmacist who makes the final evaluation. This documentation may be retained in the following manner:
- (1) If such a system provides a hard-copy printout of each day's controlled substance prescription or LTCF chart order refill data, the controlled substance refill information shall be verified, dated, and signed by the pharmacist making the final evaluation. The pharmacist shall verify that the date indicated is correct and then sign this document in the same manner as he/she would sign a check or legal document. This document shall be maintained in a separate file at the prescription drug outlet for a period of two years from the dispensing date. The printout of the day's controlled substance prescription or LTCF chart order refills must be generated by the prescription drug outlet within seventy-two 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 Rule 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 fulfillment or LTCF chart order transactions need not print the daily printout required by Rule 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 Rule 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 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 seventy-two 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 Rules.
- e. Whether the prescription drug outlet elects to comply with Rule 11.04.30 (d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:
- (1) The prescription order serial number;
 - (2) The name of the patient;
 - (3) The name of the practitioner;
 - (4) For each controlled substance dispensed, the practitioner's Drug Enforcement Administration registration number;
 - (5) The date of issue by the practitioner; if the date is omitted by the practitioner, the date dispensed shall be presumed to be the date of issue;
 - (6) The total number of refills authorized;
 - (7) Date dispensed;
 - (8) The name and strength of the drug dispensed;
 - (9) The quantity of the drug dispensed;
 - (10) In the case of a refill, the total number of refills dispensed to date;
 - (11) Whether the prescription order is a new or refill transaction;
 - (12) In the case of a controlled substance, a means of visually identifying orders for such substances and differentiating them from non-controlled substances.

11.05.00 Records Pertaining to Hospital Chart Orders.

11.05.10 A chart order or the other appropriate, uniformly maintained records permitted by Rule 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 Rules 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 Rules 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 Rule, 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 Rule 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 Rule 11.05.30 (e). For the purpose of this Rule, "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 Rule 11.05.20. These records shall be printed a minimum of every twenty-four hours unless the prescription drug outlet complies with Rule 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 seventy-two 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 seventy-two 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 rules.

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 Rule 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 Rule 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 its 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 seventy-two 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 Rules.
 - e. Whether the prescription drug outlet elects to comply with Rules 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 Rule 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
- 11.06.05 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, if pharmacy does not have a digital means of recording date of receipt into inventory;
- f. Name of the labeler of the drug and/or NDC number of the drug if it is labeled only with its generic name;
- g. Name and address of the distributor;
- h. Name and address of the receiving outlet;
- i. DEA number of distributor and receiver if a controlled substance; and
- j. If a schedule II controlled substance, the DEA Form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other. 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).

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

11.06.30 Unless authorized by Rule 11.06.50, all records of receipt of schedule II controlled substances shall be maintained separately from all other records and be readily available for inspection in hard copy form at the outlet for a period of time not less than two years from the date the drugs were received.

11.06.40 Unless authorized by Rule 11.06.50, all records of receipt of schedule III, IV, and V controlled substances shall be maintained separately from all other records and shall at all times be maintained and readily available for inspection in hard copy form at the outlet for a period of time not less than two years from the date the drugs were received.

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

- a. The prescription drug outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure;
- b. Have and maintain a complete on-line receipt file that is printable on the inspector's request; or
- c. Have a "lock-out" feature that prevents editing of receipt information;
- d. The Board or its inspectors must be able to inspect and review all of the prescription drug receipt transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:

- (1) Print a report of all prescription drug receipt transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours;
 - Or
 - (2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review prescription drug receipt transactions, and if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).
 - (3) It is the responsibility of the pharmacist manager of the outlet to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the pharmacist manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.
- e. If the outlet chooses to maintain records detailing the receipt of prescription drugs electronically, any reports printed upon the request shall contain, at a minimum, the following information for each receipt transaction:
 - (1) Name of the drug;
 - (2) Strength of the drug;
 - (3) Dosage form if appropriate;
 - (4) Quantity of the drug received;
 - (5) Date received;
 - (6) Name of the labeler of the drug and/or NDC number of the drug if it is labeled only with its generic name;
 - (7) Name and address of the distributor; and
 - (8) Name and address of the receiving outlet.

11.07.00 Distribution

11.07.10 Records of distribution of controlled substances and prescription drugs within hospitals and facilities owned and operated by a health maintenance organization (as defined in section 10-16-102, C.R.S.). Records of distribution of controlled substances and prescription drugs shall comply with the following:

- a. In a hospital or a facility owned and operated by health maintenance organization or the veterinary hospital owned and operated by Colorado State University or its successor organization which operates a registered prescription drug outlet, a controlled substance or prescription drug may be distributed for floor stock to appropriate areas within the hospital or facility. A record of any such distribution shall be made and retained by the prescription drug outlet for a period of time not less than two years and shall include the following information:

- (1) The location receiving the drug;
 - (2) The name of the drug;
 - (3) The strength of the drug;
 - (4) The quantity of the drug;
 - (5) The dosage form if appropriate;
 - (6) The date the drug was supplied;
 - (7) The identity of the person in the prescription drug outlet who issued the drug;
 - (8) The identity of the person who placed the drug into floor stock.
- b. These records of distribution may be retained electronically provided the following requirements are met:
- (1) The prescription drug outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.
 - (2) The prescription drug outlet must:
 - (a) Have and maintain a complete on-line distribution file that is printable on the inspector's request,
 - or
 - (b) Have a "lock-out" feature that prevents editing of distribution information.
 - (3) The Board and its inspectors must be able to inspect and review the distribution transactions of the prescription drug outlet. Therefore, immediately upon the oral or written request of the Board or its inspectors, the prescription drug outlet shall either:
 - (a) Print a report of all distribution transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date distributed, drug name, strength and dosage form, or
 - (b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the prescription drug outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1)

- (c) It is the responsibility of the prescription drug outlet manager to ensure that all prescription drug outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the prescription drug outlet manager and/or a staff pharmacist to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.
- (4) If the prescription drug outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:
 - (a) The location receiving the drug;
 - (b) The name of the drug;
 - (c) The strength of the drug;
 - (d) The quantity of the drug;
 - (e) The dosage form if appropriate;
 - (f) The date the drug was supplied;
 - (g) The identity of the person in the prescription drug outlet who issued the drug;
 - (h) The identity of the person who placed the drug into floor stock.

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.
 - l. The internal lot number assigned if the drug is packaged and distributed by a prescription drug outlet owned and operated by a hospital that is accredited by the Joint Commission of Accreditation of Healthcare Organizations or a successor organization or by a prescription drug outlet operated by a health maintenance organization as defined in section 10-16-102, C.R.S. Such drugs may only be distributed to prescription drug outlets under common ownership.
- 11.07.21 These records of distribution and casual sale required by Rule 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 Rule 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 Rules.
 - 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 Pharmacists and Pharmacy Interns. 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 rule; and
- d. The date upon which such person began practicing pharmacy in the prescription drug outlet.

11.08.50 List of Pharmacy Technicians and Provisional Pharmacy Technicians. Each prescription drug outlet shall keep and maintain on a current basis a list of every pharmacy technician and provisional pharmacy technician who has practiced in that outlet at any time during the previous two years after original required certification date of March 30, 2020, 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 state certification number;
- c. A sample of his/her initials and signature and any other identifying mark as affixed to any record required by law or rule; and
- d. The date upon which such person began practicing as a pharmacy technician or provisional pharmacy technician 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.

11.10.00 Off-Site Storage of Records for Pharmacies. Off-site storage of records for pharmacies shall meet the following requirements:

- a. The off-site storage of executed DEA 222 forms required controlled substance inventories, controlled substance prescription orders, and controlled substance LTCF chart orders for the two years preceding a request will not be allowed.
- b. The off-site storage of a pharmacy's employee list and any other list detailing symbols and codes as required by regulations 11.08.00 and 11.09.00, respectively, will not be allowed.
- c. If off-site storage of all other required records occurs (not detailed in Items a and b above), each pharmacy shall, at all times, maintain all required records on the premises of the pharmacy for the preceding six months.
- d. After six months, the storage of the remaining required records (not detailed in Items a and b above) for the two years proceeding a request shall meet the following requirements:
 1. The off-site storage of records shall be stored in such a manner so as to restrict unauthorized access.
 2. The off-site storage of records shall be stored in a climate-controlled environment which maintains the physical (i.e. – readable) integrity of the records.
 3. All required records maintained at an approved off-site location shall be readily available upon request of the Board or its staff within 48 hours of the request.
 4. Only one entity may be used for off-site record keeping storage. The name, web address, and contact telephone number of the storage entity will be detailed at the original pharmacy location in a readily retrievable format.
 5. The DEA registrant must send a notice declaring the off-site storage of controlled substance records to the Special Agent in Charge of the DEA in the area where the registrant is located.

11.11.00 Electronic maintenance of Schedule II, III, IV, and V controlled substance and noncontrolled substance orders. When a Prescription Drug Outlet maintains such electronic orders, it shall:

- a. The pharmacy's computer system must be backed up every 24 hours.
- b. The orders must be electronically imaged into the system as soon as received and prior to dispensing.
- c. The electronically imaged order cannot be edited.
- d. The electronically imaged orders must be electronically available and legible to the naked eye for at least two years from the date of the last transaction of the order.

- e. The Board or its inspectors must have access to the orders without delay. The pharmacy must provide a terminal and staff to assist.
- f. The pharmacy is following its posted method of recording the identities of pharmacists conducting the initial interpretation of orders and corresponding refills as well as the final evaluation of corresponding prescriptions and refills.
- g. The orders must indicate the serial number assigned to the order, the date of dispensing, the appropriate information regarding substitution, if applicable, and clarifications to the order, if applicable. If a Schedule II, III, IV, and V controlled substance prescription order, the order also must indicate the address of the practitioner and patient as well as the individual DEA registration number of the practitioner.
- h. Order information for individual orders must be printable upon request.
- i. If there are software revisions or enhancements, the system must be capable to complying with the items listed above.
- j. The computer system shall be capable of displaying, printing or creating a readily retrievable report that allows for the review of at least 600 orders per hour.
- k. All original hard copy Schedule II, III, IV, and V controlled substance prescription orders shall be maintained by the prescription drug outlet in accordance with all applicable federal rules and laws.
- l. All electronically transmitted prescription orders shall be electronically available and legible for at least two years from the date of latest transaction related to the order.
- m. If the pharmacy's computer system has functionality that allows the user to search for and retrieve electronically maintained orders by assigned serial number, the orders will be deemed readily retrievable. In the absence of such functionality, electronically maintained orders must be stored or displayed sequentially by serial number.
- n. A complaint against the Pharmacy may be opened if one or more of the following are determined during the course of an inspection or investigation:
 - 1. Electronically imaged orders are in fact being edited;
 - 2. Imaged orders are not consistently available in electronic form for the past 2 years;
 - 3. No terminal or staff is available to the inspector to review orders;
 - 4. Individual order information cannot be consistently printed; or
 - 5. The computer system is not capable of displaying for review at least 600 orders per hour.
- o. If a pharmacy stops maintaining records electronically, the pharmacy must maintain all hard-copy prescription orders in one of three separate files (one for noncontrolled substance orders, another for Schedule III, IV and V controlled substance orders, and another for Schedule II controlled substance orders) and in numerical sequence by serial number as assigned to each order by the pharmacy until it can resume to maintain them electronically according to requirements.

12.00.00 NUCLEAR PHARMACY.

- 12.00.10 Authorized handling. It is unlawful for any person to provide radiopharmaceutical services unless he or she is a nuclear pharmacist acting in accordance with Title 12, Article 280, C.R.S., and the Rules of the Board and rules of the Colorado Department of Public Health and Environment, 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 section 25-11-101 *et seq.*, C.R.S. The requirements of this Rule are in addition to, and not in substitution for, other applicable provisions of Rules of the Board and the State Radiation Control Agency.
- 12.00.20 Definitions.
- 12.00.21 "Nuclear prescription drug outlet" means a prescription drug outlet which deals with the preparation and delivery of radioactive material as defined in section 25-11-101, C.R.S.
- 12.00.22 "Nuclear pharmacist" means a pharmacist who holds an active pharmacist license with the Board and has met the standards of training and experience for "Authorized User Status" in handling radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission.
- 12.00.23 "Radiopharmaceutical service" shall mean, but shall not be limited to, the compounding, dispensing, labeling and delivery of radiopharmaceuticals; the participation in radiopharmaceutical selection and radiopharmaceutical utilization reviews; the proper and safe storage and distribution of radiopharmaceuticals; the maintenance of radiopharmaceutical quality assurance; the responsibility for advising, where necessary or where regulated, of therapeutic values, hazards, and use of radiopharmaceuticals, and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of radiopharmaceuticals.
- 12.00.24 "Radiopharmaceutical" is any drug which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or protons and includes any such drug which is intended to be made radioactive. This definition includes non-radioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.
- 12.00.25 "Radiopharmaceutical quality assurance" means, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.
- 12.00.26 "Internal test assessment" means, but is not limited to, conducting those tests of quality assurance necessary to ensure the integrity of the test.
- 12.00.27 "Authentication of product history" means, but is not limited to, identifying the purchasing source, the ultimate fate, and intermediate handling of any component of a radiopharmaceutical.
- 12.00.28 "Authorized practitioner" means a practitioner authorized by law to possess, use and administer radiopharmaceuticals, acting within the scope of such authority.

- 12.00.30 Requirements For Nuclear Prescription Drug Outlets. A nuclear prescription drug outlet shall only be managed by a nuclear pharmacist. All personnel performing tasks in the preparation and distribution of radiopharmaceuticals shall be under the direct supervision of a nuclear pharmacist. A nuclear pharmacist shall be in attendance at all times that the nuclear prescription drug outlet is open for business and shall be responsible for all operations of the registered area.
- 12.00.31 All nuclear prescription drug outlets shall have adequate space, commensurate with the scope of services required and provided. The nuclear prescription drug outlet area shall be separate from the areas for non-radioactive drugs and shall provide a radioactive storage and product decay area separate from and exclusive of the radioactive laboratory, compounding, dispensing, quality assurance and administrative area. Prior to registration, a nuclear prescription drug outlet that wishes to compound both radiopharmaceuticals and non-radiopharmaceuticals not directly pertaining to nuclear studies shall meet the space requirements set forth in Rule 5.01.31. If a nuclear prescription drug outlet wishes to compound only radiopharmaceuticals, it shall not be required to meet the space requirements set forth in Rule 5.01.31. All nuclear prescription drug outlets shall submit detailing drawing-to-scale floor plans to the Board that have been approved by the state radiation control agency before approval of the registration.
- 12.00.32 There shall be a professional reference library available in the nuclear 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 Title 12, Article 280, C.R.S.; 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 hazardous products, Technical Manual Section VI: Chapter 2, Controlling Occupational Exposure to Hazardous Drugs or ASHP Technical Assistance Bulletin on Handling Cytotoxic and Hazardous Drugs;
 - (7) Any other references that the pharmacist manager of the prescription drug outlet may deem necessary; and
 - (8) The current rules of the State Radiation Control Agency and U.S. Nuclear Commission.
- 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 rules governing non-radioactive drugs.
- 12.00.34 A nuclear prescription drug outlet shall have adequate equipment commensurate with the scope of radiopharmaceutical services to be provided.
- 12.00.35 Nuclear prescription drug outlets which compound and dispense only radiopharmaceuticals shall be exempt from the security requirements of Rule 5.01.50 provided the following conditions are met:

- a. Only individuals identified as having “Authorized User” status by the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission may enter the compounding/dispensing area in the absence of a pharmacist and only for the purpose of equipment maintenance.
- b. The nuclear prescription drug outlet maintains a written record documenting such entry detailing the following information:
 - 1) Date and time of entry;
 - 2) Authorized users name;
 - 3) Reason for entry; and
 - 4) Signature of pharmacist manager.

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

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

- a. Be a pharmacist licensed to practice in Colorado;
- b. Meet the standards of training and experience for “authorized user status” in handling of radioactive materials in accordance with either the State Radiation Control Agency or the U.S. Nuclear Regulatory Commission; and
- c. Be specifically identified, by name, as an “authorized nuclear pharmacist” on either a radioactive materials license issued by the Colorado Department of Public Health and Environment or on a U.S. Nuclear Regulatory Commission master license.

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

- a. The original copy of the current registration with the pharmacy board;
- b. The original copy, or a reference to its specific location in the outlet, of the most current radioactive materials license issued by the Colorado Department of Public Health and Environment;
- c. A copy, or a reference to its specific location in the outlet, of the most current U.S. Nuclear Regulatory Commission master license which details a listing of its authorized nuclear pharmacists if the current radioactive license issued by the Colorado Department of Public Health and Environment references the outlet’s U.S. Nuclear Regulatory Commission master license rather than detailing a listing of the outlet’s authorized nuclear pharmacists itself; and
- d. The outlet’s current list of employees that complies with Rule 11.08.00.

12.00.64 Nuclear Compounding.

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

- a. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the final compounded product.
- b. The compounding of sterile radiopharmaceuticals shall comply with Rule 21.00.00, including all recordkeeping requirements.

12.00.70 Dispensing.

- a. A radiopharmaceutical shall only be dispensed pursuant to a valid, patient-specific prescription order that is issued by an authorized practitioner.
- b. A nuclear prescription drug outlet shall only dispense radiopharmaceuticals which comply with acceptable standards of radiopharmaceutical assurance.
- c. In addition to any labeling requirement of the Board for nonradiopharmaceuticals, the immediate outer container of the radiopharmaceutical to be dispensed shall also be labeled with:
 - (1) The standard radiation symbol;
 - (2) The words "Caution – Radioactive Material";
 - (3) The name of the radiopharmaceutical;
 - (3) The amount of radioactive materials contained, in millicuries or microcuries;
 - (4) If a liquid, the volume in milliliters;
 - (5) The requested calibration time for the amount of radioactivity contained; and
 - (6) Expiration data, if applicable.
- d. The immediate inner container shall be labeled with:
 - (1) The standard radiation symbol;
 - (2) The words "caution – radioactive material";
 - (3) The assigned serial number of the corresponding prescription order; and
 - (4) The name of the radiopharmaceutical.
- e. The amount of radioactivity shall be determined by radiometric methods for each individual preparation immediately prior to dispensing.

12.00.71 Records of Dispensing.

- a. In addition to any requirement of the board for non-radiopharmaceutical prescription orders, the prescription order shall include the following:
 - (1) Address of the authorized practitioner and/or the address where the prescription is to be administered;
 - (2) The name of radiopharmaceutical;

- (3) The amount of radioactive materials contained, in millicuries or microcuries; and
- (4) Calibration time for the amount of radioactivity contained.

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

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

12.00.72 Distribution.

- a. A nuclear prescription drug outlet may distribute a compounded radiopharmaceutical to a practitioner authorized by law to prescribe the drug for the purposes of administration. Such distributions shall be limited to up to ten percent of the total number of drug dosage units dispensed and distributed on an annual basis by such outlet.
- b. A nuclear prescription drug outlet may redistribute NDA approved radiopharmaceuticals if the outlet does not process the radiopharmaceuticals in any manner or violate the product packaging.
- c. The immediate outer container of the radiopharmaceutical to be distributed shall be labeled with:
 - (1) The standard radiation symbol;
 - (2) The words "Caution – Radioactive Material";
 - (3) "RX Only";
 - (4) The name of Radiopharmaceutical;
 - (5) The amount of radioactive materials contained, in millicuries or microcuries;
 - (6) If a liquid, the volume in milliliters;
 - (7) The requested calibration time for the amount of radioactivity contained;
 - (8) Expiration data, if applicable;
 - (9) The assigned batch (lot) number;
 - (10) Specific route of administration;
 - (11) Storage directions; and
 - (12) The name and address of the prescription drug outlet.

d. The immediate inner container shall be labeled with:

- (1) The standard radiation symbol;
- (2) The words "Caution – Radioactive Material";
- (3) The assigned batch (lot) number; and
- (4) The name of the radiopharmaceutical.

12.00.73 Records of Distribution.

- a. A nuclear prescription drug outlet shall maintain records of acquisition and distribution of all radiopharmaceuticals in accordance with Title 12 and Title 25, C.R.S.
- b. A nuclear prescription drug outlet must retain verification of each practitioner's license from the jurisdiction in which licensed on a current basis for each practitioner to whom it distributes compounded radiopharmaceuticals.
- c. A nuclear prescription drug outlet that distributes radiopharmaceuticals shall record the following:
 - (1) The name of the radiopharmaceutical;
 - (2) The amount of radioactive materials contained, in millicuries or microcuries;
 - (3) If a liquid, the volume in milliliters;
 - (4) The requested calibration time for the amount of radioactivity contained;
 - (5) The date of distribution;
 - (6) The name and address of the authorized practitioner and the address where the preparation is to be administered; and
 - (7) The name and address of the distributing outlet.
- d. Records of distribution shall be retained at the outlet for a period of not less than two years from the date of distribution.

13.00.00 DECLARATORY ORDERS.

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

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

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

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

- a. Whether a ruling on the petition will terminate a controversy or remove uncertainties as to the applicability to petitioner of any statutory provision or rule or order of the Board.
 - b. Whether the petition involves any subject, question, or issue which is the subject of a formal or informal matter or investigation currently pending before the Board or a court but not involving any petitioner. Whether the petition seeks a ruling on a moot or hypothetical question or will result in an advisory ruling or opinion.
 - c. Whether the petitioner has some other adequate legal remedy, other than an action for declaratory relief pursuant to Rule 57 Colorado Rules of Civil Procedure, which will terminate the controversy or remove any uncertainty as to the applicability to the petitioner of the statute, rule or order in question.
- 13.00.13 Any petition filed pursuant to this Rule shall set forth the following:
- a. The name and address of the petitioner and whether the petitioner is licensed pursuant to the provisions of section 12-280-101, *et seq.*, C.R.S., 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 (section 24-4-105(8), C.R.S.) 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 section 24-4-106, C.R.S.

14.00.00 OTHER OUTLETS.

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

- a. Hospitals that do not operate registered prescription drug outlets. For such hospitals, dispensing shall be limited as provided in section 12-280-120(10), C.R.S.;
- b. Federal Federally Qualified Health Centers, as defined by the federal "Social Security Act";
- c. Family Planning Clinics;
- d. Colleges, universities and schools (grades kindergarten through twelve) which operate a school-based clinic for students and faculty of that school. Schools must submit any contractual affiliations to the Board prior to registration;
- e. Jails. A jail which obtains prescription drugs solely on the basis of individual prescription orders which have been compounded in and dispensed from a registered prescription drug outlet do not need registration;
- f. County or district public health agencies;
- g. Community and Rural Health Clinics, registered, certified, or licensed as such as by the Colorado Department of Public Health and Environment;
- h. Ambulatory Surgical Centers licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S., that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;
- i. Medical Clinics operated by a hospital that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;

- j. Hospices licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S., that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;
 - k. Acute treatment units, registered, certified, or licensed as such by the Colorado Department of Public Health and Environment;
 - l. Convalescent centers registered, certified, or licensed as such by the Colorado Department of Public Health and Environment;
 - m. Community Mental Health Clinic having the same meaning as set for in section 25-27.6-102(9), C.R.S.;
 - n. Behavioral Health Entity as defined in section 25-27.6-102(6), licensed pursuant to Article 27.6 of Title 25, C.R.S.; and
 - o. Approved Treatment Facility that is an approved private or public treatment facility, as described in section 27-81-102(2) and (3) that adheres to the standards set forth in section 27-81-106, C.R.S.
- 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 section 12-280-119(1)(d), C.R.S., are stated below.
- a. For the purpose of this section, the consultant pharmacist is the pharmacist responsible for the other outlet registration and the overall operation pertaining to drug receipt and distribution.
 - b. Except as provided in Rule 14.07.00, all prescription drugs utilized by the outlet shall be obtained from an entity or individual registered with the Board or a state or local health agency.
 - c. For the purposes of this Rule, "dispensing unit" means a container or containers of a drug, either packaged pursuant to Rule 3.01.00 or the manufacturer's original container(s), containing a quantity suitable for the prescribed treatment or condition.
- 14.00.20 Policy and Procedure Manual. Written policies shall be developed by the consultant pharmacist and the consultant pharmacist shall assure that the Other Outlet has policy and procedure manual available for inspection which addresses the receipt, storage, dispensing, prepackaging, compounding and other disposition of prescription drugs and controlled substances, and that that the consultant pharmacist reviews, dates and signs the manual at least once annually.. These policies shall include:
- 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.

- 14.00.40 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.
 - b. If a CDPHE Certificate is required by law, then a copy of the CDPHE certificate will be provided as part of the application.
 - c. Other outlet relocation. When an other outlet changes location, the outlet shall submit an application on a form provided by the Board within thirty (30) days prior to the expected outlet relocation.
 - d. Change of ownerships of other outlet. Application to transfer registration of an other outlet shall be submitted on a form provided by the Board within thirty (30) days prior to the expected change of ownership. This application shall be accompanied by the appropriate fee. 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 twenty 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 twenty 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 twenty percent or more of the membership interests.
 - (4) Upon incorporation of an existing other outlet.
 - e. 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.
 - f. Change of consultant pharmacist.
 - (1) A new application shall be submitted to the Board within thirty days after the former consultant pharmacist ceases to be the consultant pharmacist.
 - (2) If an application is not submitted within thirty 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 internal policies and document the review within thirty 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.
 - g. Change of Registration.
 - (1) Any other outlet located in a community health clinic, rural health clinic, college, or university which dispenses more than 25,000 dispensing units in a calendar year shall register with the Board as a prescription drug outlet.
 - (2) Any other outlet located in a hospital which has greater than 25 beds as stated on its license with the Colorado Department of Public Health and Environment shall register as a prescription drug outlet.
 - h. Reinstatement of Registration. If an Other Outlet registration has expired, a registrant wishing to reinstate such registration shall submit the following: The current reinstatement application with the required fee.
- 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 policies, 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 policy for dispensing by unlicensed persons.
 - b. A consultant pharmacist shall be available for professional consultation.
 - c. A consultant pharmacist shall annually review the policies for compliance with this Rule 14.00.00. The review shall be documented in writing, signed, and dated by the consultant pharmacist. The consultant pharmacist shall record on the protocols at least annually the number of dispensing units dispensed in a calendar year for the following facility types: community clinics, rural health clinics, colleges, and universities. A calendar year is considered to run from January 1 through December 31.
 - d. The consultant pharmacist shall develop an inspection form to document the visit and the results thereof. Such form shall be dated and signed by the consultant pharmacist and shall be maintained and available for inspection at the other outlet by the Board for a period of two years.
 - e. The consultant pharmacist shall inspect and document the inspection in writing as detailed in 14.00.80(d) the following other outlets at the following frequencies:

- (1) Quarterly inspections and visits shall be conducted for the following:
 - (a) Jails;
 - (b) County health departments;
 - (c) Schools, grade kindergarten through twelve;
 - (d) Hospitals;
 - (e) Family planning clinics;
 - (f) Hospices;
 - (g) Medical clinics operated by hospitals;
 - (h) Ambulatory Surgical Centers;
 - (i) Convalescent centers;
 - (j) Community mental health clinic;
 - (k) Behavioral health entity; and
 - (l) Approved treatment facility.
 - (2) Community clinics, federally qualified health centers, rural health clinics, colleges, acute treatment units, and universities shall be inspected and visited as follows:
 - (a) Monthly if 2,500 or less dispensing units are dispensed in a calendar year. A calendar year is from January 1 through December 31.
 - (b) Every other week if 2,500 or more but less than 7,501 dispensing units are dispensed in a calendar year. A calendar year is from January 1 through December 31.
 - (c) Each week if 7,501 or more but less than 12,501 dispensing units are dispensed in a calendar year. A calendar year is from January 1 through December 31.
 - (d) Twice each week if 12,501 or more but less than 25,001 dispensing units are dispensed in a calendar year. A calendar year is from January 1 through December 31.
- f. The consultant pharmacist shall be responsible for the accuracy of records pertaining to drug stock returned to the original supplier, the manufacturer, or via a reverse distributor. The record of any returned drug stock shall indicate, as a minimum, the name and address of the original supplier, manufacturer or reverse distributor, the date of return, and the name, strength, and quantity of the drug returned. This record shall be signed by the consultant pharmacist, and shall be maintained on the premises for a minimum of two years.

- g. The consultant pharmacist for a licensed hospital other outlet shall be notified of any casual sale or loan of a drug made by the licensed hospital other outlet to a practitioner authorized by law to prescribe the same prior to the transaction. The consultant pharmacist for a licensed hospital other outlet shall be notified within seventy-two hours of any casual sale or loan of a drug to a registered other outlet, a prescription drug outlet, or a mobile emergency care unit.
- h. The consultant pharmacist is responsible for ensuring all prescription drugs obtained by the other outlet are procured from an individual or entity registered by the Board or a state or local health agency.
- i. The consultant pharmacist shall be responsible for ensuring any significant errors related to the practice of pharmacy, such as those that result in significant harm to a patient or the death of a patient, are immediately reported to the Board upon discovery.
- j. The consultant pharmacist shall be responsible for assuring that the other outlet complies with all applicable provisions of Rule 21.00.00 when compounding non-sterile and sterile products.
- k. The consultant pharmacist shall be responsible for reporting diversion, theft or significant unaccountable loss of prescription drugs or controlled substances from the other outlet, hospital or health maintenance organization (as defined in section 10-16-102, C.R.S.) within one business day of discovery. When a Drug Enforcement Administration (DEA) Form 106 is submitted to the DEA in instances involving controlled substances, a copy of the completed DEA Form 106 along with a detailed written explanation shall be submitted to the Board. When determining whether an unaccountable loss is significant, the consultant pharmacist shall consider, among others factors, the following:
 - (1) The actual quantity of drug lost in relation to the type of business;
 - (2) The specific drug lost;
 - (3) Whether the loss of the drug can be associated with access to those drugs by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drug;
 - (4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;
 - (5) Whether the specific drug is a likely candidate for diversion; and
 - (6) Local trends and other indicators of the diversion potential of the missing drug.

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 ninety 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 ninety days, an application identifying a new consultant pharmacist shall be submitted to the Board no later than thirty days following the end of the original ninety day period.

14.02.00 Records and recordkeeping in other outlets.

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

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

a. For all other outlets:

- (1) The following records shall be maintained on the premises of the other outlet at all times and shall be made available for inspection by the Board or its inspectors immediately upon request.
 - (a) All DEA-222 forms executed during the two years preceding the request;
 - (b) All inventories of controlled substances required to be taken during the two years preceding the request;
 - (c) All records of dispensing, receipt (invoices for drugs received and drugs credited), distribution, loss, surrender or disposal in any other manner of prescription drugs and controlled substances during the two years preceding the request;
- (2) The following records shall be made available within forty-eight 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 forty-eight 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(s) the inventory is taken. The inventory shall be maintained in written, typewritten, electronic, 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 twenty-four hours per day, the inventory shall specify the time the inventory was conducted.
 - 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), or the veterinary hospital owned and operated by Colorado State University or its successor organization, the inventory may be taken over 72 hours multiple days if:
 - (1) Inventory is secured in automated dispensing machines
 - (2) Inventory is counted with a witness
 - (3) The date, time and users performing the count are electronically recorded and reported separately on the inventory for each medication storage bin
 - e. After the initial inventory is taken, the other outlet shall take a new inventory of all stocks of controlled substances on hand at each consultant pharmacist visit at a frequency determined pursuant to 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.

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- f. 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.
 - g. 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.
 - h. 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.
 - i. 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;
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- (12) If a controlled substance, the Drug Enforcement Administration registration number of the prescriber;
- (13) In the case of other outlet off-site dispensing, dispensing records shall distinguish between on-site and off-site transactions.

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

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

- a. All new and refill transactions shall be entered into the system at the time of the transaction, except as provided in Rule 14.03.10 i.
- b. Every twenty-four hours, except as provided in Rule 14.03.20, the system must produce a hard-copy document which, for the purposes of these Rules, shall be known as the "daily printout". It shall consist of a single, uniform, complete document, except as otherwise permitted by this Rule. The daily printout shall list, separately, each prescription order transaction for the previous twenty-four hours and shall contain all information required by this Rule. Daily printouts shall be retained in a chronological manner. If the printouts are bound, the sheets shall be separated into individual pages which are then placed in the same order as printed and bound uniformly. If the pages are bound in any other manner so that they are not uniform in placement or appearance, they shall be deemed not readily retrievable and available.
- c. The daily printout shall contain all of the following information for each dispensing transaction and shall differentiate between new and refill transactions. As an alternative, new and refill transactions may be separated into two separate uniform and complete documents which contain the following:
 - (1) The serial number;
 - (2) The name of the patient;
 - (3) The name of the practitioner;
 - (4) For each controlled substance dispensed, the practitioner's Drug Enforcement Administration registration number;
 - (5) The date of issue by the practitioner. If the date is omitted by the practitioner, the date dispensed shall be presumed to be the date of issue;
 - (6) The total number of refills authorized;
 - (7) The date dispensed;
 - (8) The initials, name, or secure electronic identifier of the individual making the final evaluation;
 - (9) The name and strength of the drug dispensed;
 - (10) The quantity of the drug dispensed;
 - (11) In the case of a refill, the total number of refills dispensed to date.

- (12) In the case of other outlet off-site dispensing, dispensing records shall distinguish between on-site and off-site transactions.
- 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 seventy-two hours from the most recent date recorded on the printout. In the case of other outlet off-site dispensing, dispensing records shall distinguish between on-site and off-site transactions.
- 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 seventy-two hours of the date on which the refill was dispensed. It must be verified and signed by each person who is involved in dispensing controlled substance refills.
- OR
- (2) The other outlet shall maintain a bound log book, or separate file, in which each person involved in dispensing controlled substance refills shall sign attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. Such a book or file must be maintained at the other outlet for a period of two years after the date of dispensing the appropriately authorized refill.
- g. The daily printout shall contain all information as required by this Rule except that the identity of the person who makes the final evaluation may appear either on the daily printout or on another separate, uniformly maintained and readily retrievable record. The consultant pharmacist shall determine which of the two methods for identifying the responsible person is more appropriate for the outlet, and only that method for recording such information shall be used.
- h. Because of the potential for a system malfunction or failure, the other outlet must have a manual procedure for recording all dispensing transactions during the system failure or malfunction. All recoverable transaction data and all manually recorded transaction data shall be entered or restored into the system within a reasonable period of time not to exceed seven days following the restoration of operation of the system.
- i. Any automated data processing system used by an outlet shall maintain the confidentiality of records in accordance with applicable laws, rules and regulations.

- 14.03.20 Electronic maintenance of dispensing records. An other outlet which utilizes a computer (automated data processing system) for storage and retrieval of information regarding dispensing transactions need not print the daily printout required by Rule 14.03.10 if the other outlet and the computer system utilized are capable of complying with the following requirements:
- a. The other outlet must be able to provide on-line retrieval of all information required by this Rule for all dispensing transactions during the two years preceding the request.
 - b. The other outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.
 - c. The other outlet must:
 - (1) Have and maintain a complete on-line transaction file that is printable on the inspector's request,
 - or
 - (2) Have a "lock-out" feature that prevents editing of dispensing information.
 - d. The Board or its inspectors must be able to inspect and review the dispensing transactions of the other outlet. Therefore, immediately upon the oral or written request of the Board or its inspectors, the other outlet shall either:
 - (1) Print a report of all dispensing transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date dispensed; drug name, strength and dosage form; patient name, and practitioner name;
 - or
 - (2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review dispensing transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the other outlet elects to comply with this subparagraph (d), the system must also be capable of printing the same reports described in subparagraph (1).
 - (3) It is the responsibility of the consultant pharmacist to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the consultant pharmacist and/or outlet staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.
 - e. Whether the other outlet elects to comply with Rule 14.03.20(d), the system and any reports printed on request shall contain, as a minimum, the following information for each transaction:
 - (1) The prescription order serial number;
 - (2) The name of the patient;
 - (3) The name of the practitioner;

- (4) For each controlled substance dispensed, the practitioner's Drug Enforcement Administration registration number;
- (5) The date of issue by the practitioner; if the date is omitted by the practitioner, the date dispensed shall be presumed to be the date of issue;
- (6) The total number of refills authorized;
- (7) Date dispensed;
- (8) The initials or other means of identification of the individual dispensing the order;
- (9) The name and strength of the drug dispensed;
- (10) The quantity of the drug dispensed;
- (11) In the case of a refill, the total number of refills dispensed to date;
- (12) Whether the prescription order is a new or refill transaction;
- (13) In the case of a controlled substance, a means of visually identifying orders for such substances and differentiating them from non-controlled substances.

14.03.30 Off-Site Administration and Dispensing of Medication

- a. An other outlet may allow a designated individual to remove medications for the purpose of dispensing and administering at an Off-Site location, provided the following requirements are met:
 - (1) The other outlet maintains records which detail the removal of the medications with at least the following information:
 - (a) Name, strength, dosage form, and NDC number of the medication removed;
 - (b) Quantity removed;
 - (c) Date removed;
 - (d) Name and title of designated individual removing the medication.
 - (2) The medications are properly stored at compendial temperatures during transport and storage at the off-site location.
 - (3) The medications shall be secured during transport and stored at the off-site location so as to allow only persons affiliated with the other outlet to have access to them.
 - (4) The remaining medications shall be returned to the other outlet the day they were removed.
 - (5) The other outlet shall maintain records detailing the medications returned with at least the following information:

- (a) Name, strength, dosage form, and NDC number of the medications returned;
 - (b) Quantity returned;
 - (c) Date returned; and
 - (d) Name and title of designated individual returning the medication.
- (6) All requirements for labeling (3.00.30) and dispensing logs (14.03.00) are satisfied and shall reflect the registered on-site location address in all transactions.
- (7) All required records shall be maintained in a manner that is uniformly maintained, readily retrievable, and available for inspection for a period of two years from the date of removal of medications for off-site administration and dispensing.

14.04.00 Receipts.

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

- a. Name of the drug;
- b. Strength of the drug;
- c. Dosage form if appropriate;
- d. Quantity received;
- e. Date received if a controlled substance;
- f. Name of the labeler of the drug if it is labeled only with its generic name;
- g. Name of the distributor;
- h. Drug Enforcement Administration number of distributor if a controlled substance.
- i. The DEA form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other.

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

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

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

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

14.05.00 Distribution.

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

- a. In a hospital which operates a registered hospital other outlet, a controlled substance or prescription drug may be distributed for floor stock to appropriate areas of the facility. A record of any such distribution shall be made and retained for a period of time not less than two years and shall include the following information:
 - (1) The location receiving the drug;
 - (2) The name of the drug;
 - (3) The strength of the drug;
 - (4) The quantity of the drug;
 - (5) The dosage form if appropriate;
 - (6) The date the drug was supplied;
 - (7) The identity of the person in the prescription drug outlet who issued the drug;
 - (8) The identity of the person who received the drug into floor stock.
- b. These records of distribution may be retained electronically provided the following requirements are met:
 - (1) The other outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.
 - (2) The other outlet must:
 - (a) Have and maintain a complete on-line distribution file that is printable on the inspector's request,
 - or
 - (b) Have a "lock-out" feature that prevents editing of distribution information.
 - (3) The Board or its inspectors must be able to inspect and review the distribution transactions of the other outlet. Therefore, immediately upon the oral or written request of the Board or its inspectors, the prescription drug outlet shall either:
 - (a) Print a report of all distribution transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date distributed, drug name, strength and dosage form;
 - or

- (b) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the other outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).
 - (c) It is the responsibility of the consultant pharmacist to ensure that all other outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the consultant pharmacist and/or outlet staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.
- (4) If the other outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:
 - (a) The location receiving the drug;
 - (b) The name of the drug;
 - (c) The strength of the drug;
 - (d) The quantity of the drug;
 - (e) The dosage form if appropriate;
 - (f) The date the drug was supplied;
 - (g) The identity of the person in the prescription drug outlet who issued the drug;
 - (h) The identity of the person who received the drug into floor stock.

14.05.11 A registered other outlet may distribute prescription drugs to another registered other outlet. 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 registered 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 Rule 14.05.20 shall be retained for a period of time not less than two years from the date of the distribution.

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

- a. The other outlet must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.
- b. Have and maintain a complete on-line distribution file that is printable on the inspector's request,

or
- c. Have a "lock-out" feature that prevents editing of distribution information.
- d. The Board or its inspectors must be able to inspect and review the distribution transactions of the other outlet. Therefore, immediately upon the oral or written request of the Board or its inspectors, the other outlet shall either:
 - (1) Print a report of all distribution transactions for such period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to, date of distribution; drug name, strength and dosage form; and licensee receiving the distribution;

or
 - (2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the other outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1).
 - (3) It is the responsibility of the consultant pharmacist to ensure that all outlet staff are aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the consultant pharmacist and/or outlet staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.

- e. If the other outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:
 - (1) The name of the drug;
 - (2) The strength of the drug;
 - (3) The dosage form if appropriate;
 - (4) The quantity of the drug;
 - (5) The manufacturer name or NDC number of the labeler of the drug if labeled only with its generic name;
 - (6) The date of distribution;
 - (7) The name, and address of the distributing outlet;
 - (8) The name, and address of the receiving practitioner or registered outlet;
 - (9) If a controlled substance is distributed, the record shall also indicate the Drug Enforcement registration number of the distributing outlet and the receiving practitioner or registered outlet.

14.05.24 Advertising.

- a. Only one address shall appear on a prescription label and that shall be the address of the other outlet from which the prescription was dispensed.
- b. An other outlet shall only use, operate or advertise under the name that appears on the current registration issued by the Board.
- c. An other outlet may not advertise, either orally or in writing, that it is a prescription drug outlet (pharmacy).

14.06.00 Petition for a Reduced /Inspection Schedule.

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

14.07.00 Emergency Redistribution of Prescription Drugs

- a. In the event of a shortage of medication or state or national emergency as dictated by either the Centers for Disease Control and Prevention (CDC) or the Colorado Department of Public Health and Environment (CDPHE), an other outlet located in a county health department or public health agency as defined in CRS 25-1-502 may obtain medications from facilities, physicians, and other entities in possession of the drugs, and redistribute the medication as directed by the CDC or CDPHE. The other outlet shall not be required to become licensed as a wholesaler to conduct distribution of drugs for the limited purpose set forth in this Rule. The other outlet shall maintain written records of the distributions detailing the following:
 - a. The name of the drug;
 - b. The strength of the drug;
 - c. The dosage form if appropriate;
 - d. The quantity of the drug;
 - e. Lot number of the drug;
 - f. Expiration date of the drug;
 - g. The name of the manufacturer or the NDC number of the drug if labeled only with its generic name.
 - h. The date of distribution;
 - i. The name and address of the distributing outlet;
 - j. The name and address of the receiver;
 - k. If a controlled substance is distributed, the record shall also indicate the drug enforcement administration registration number of the distributing outlet and the receiver.
 - l. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form.

15.00.00 WHOLESALERS.

15.01.00 Wholesale Drugs Distributor Registration Requirement.

- a. A wholesaler means a person engaged in the wholesale distribution of prescription drugs to persons, other than consumers, that are authorized by law to possess prescription drugs.
- b. Every wholesaler must be registered with the Board 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.

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- 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 section 12-280-304, C.R.S.
 - (9) Wholesalers that distribute animal health medicines exclusively must have a designated representative. However, the requirement of 15.01.11a(8) is not required. For the purpose of this Rule 15.00.00, an "animal health medicine" means a prescription drug, regardless of whether the drug is originally intended for humans or animals, that will be distributed by a wholesaler only to an animal pursuant to an order issued by a veterinarian or directly to a veterinarian authorized by law to prescribe the drug.
 - b. Any registered wholesale drug distributor that is accredited by a Board approved accreditation body shall inform the Board, in writing, within seventy-two hours if its accreditation is:
 - (1) Expired;
 - (2) Suspended;
 - (3) Revoked; or
 - (4) Withdrawn.
 - c. An out-of-state wholesaler's Colorado registration shall be deemed void and shall be cancelled if the wholesaler relocates to a state other than that which is listed on its Colorado registration. In the event the wholesaler wishes to continue distributing prescription drugs into and within Colorado, it must apply for and receive a new Colorado registration indicating its current state of residence.
 - d. A wholesaler's Colorado registration shall be deemed void and shall be cancelled if it was registered in Colorado using an inspection from a board-approved accreditation body and the accreditation issued by that accreditation body is revoked or withdrawn.
- 15.01.12 Minimum Qualifications.
- a. The Board shall consider, at a minimum, the following factors in reviewing the qualifications of persons of businesses described in Rule 15.01.11 above who engage in the wholesale distribution of prescription drugs within the state:

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- (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 Board considers relevant to and consistent with the public health and safety.
- b. The Board 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 five years prior to registration. If the applicant is located in Colorado, inspectors from the Board shall conduct the inspection. If the wholesaler is located outside of Colorado, the board of pharmacy of the state in which the wholesaler resides shall conduct an inspection of the facility or the out of state wholesaler may be inspected by a Board-approved accreditation body.
 - d. The Board may suspend, revoke, refuse to renew, or otherwise discipline the registration of any wholesale drug distributor if its Board approved accreditation has been suspended, revoked, or withdrawn.
- 15.01.13 A wholesaler must be located at a commercial location. It may not be located in a personal dwelling or residence.
- 15.01.14 Change of name, location, or ownership, or designated representative.
- a. Any change in the name or location of the wholesaler shall be reported to the Board on an application provided by the Board within thirty (30) days of such change.
 - b. Any change in ownership shall be reported on an application provided by the Board within thirty (30) days prior to the change, with a final notice of the ownership change reported to the Board the day of such change. The new owner(s) shall 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 twenty 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 twenty 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 twenty 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 thirty calendar days of such change. The incoming designated representative must undergo the required background check.
- 15.01.17 When a wholesaler changes location, the outlet shall submit an application on a form provided by the Board within thirty (30) days prior to outlet relocation.
- 15.01.18 Reinstatement of an Expired In-State or Out-of-State Prescription Drug Wholesaler Registration.
- a. In-State Prescription Drug Wholesaler. If a registration has expired, a registrant wishing to reinstate such registration shall submit the following:
 - (1) The current reinstatement application with the required fee;
 - (2) A newly completed designated representative affidavit, on a form provided by the Board, that is signed and dated by the designated representative; and
 - (3) If a different designated representative has been established for the applicant since the expiration of the registration, the applicant shall submit the new designated representative's fingerprints to the Colorado Bureau of Investigation for both a state and federal background check at the time of submission of the reinstatement application, unless otherwise statutorily exempt or previously waived by the Board.
 - b. Out-of-State Prescription Drug Wholesaler. If a registration has expired, a registrant wishing to reinstate such registration shall submit the following:
 - (1) The current reinstatement application with the required fee;
 - (2) The applicant shall submit the designated representative's fingerprints to the Colorado Bureau of Investigation for both a state and federal background check at the time of submission of the reinstatement application, unless otherwise statutorily exempt or previously waived by the Board.
 - (3) A verification of the current prescription drug wholesaler license or registration issued by the resident state board of pharmacy;
 - (4) A newly completed designated representative affidavit, on a form provided by the Board, that is signed and dated by the designated representative; and
 - (5) If the registration has expired for over two years, a registrant shall submit one of the following:
 - (A) A copy of a report detailing an inspection of the out-of-state prescription drug wholesaler by its resident state board of pharmacy dated within two years of submission of the reinstatement application; or

- (B) A current copy of the wholesaler's accreditation by a board-approved accreditation body; or
- (C) Proof of the wholesaler's current registration with the Federal Food and Drug Administration (FDA).

15.02.00 Personnel.

15.02.10 Designated Representative. A single person shall be designated by name and title who has complete and overall responsibility for the operation of the facility in compliance with all applicable laws rules pertaining to drugs and devices. This person's name 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 has 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 Drug Enforcement Administration 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 Rule 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 Rule 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 Rule 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 business days.

15.08.15 Any drug or device that has been opened or used, but is not adulterated, misbranded, counterfeited, or suspect of being counterfeit, shall be identified as such, and shall be quarantined and physically separated from other drugs or devices until they are returned to the manufacturer or wholesale distributor from which acquired or destroyed.

15.08.16 Contraband, counterfeit, or suspected to be counterfeit drugs and devices, other evidence of criminal activity, and accompanying documentation shall be retained and not destroyed until its disposition is authorized by the Board and FDA.

15.08.17 The shipping container, immediate or sealed outer or secondary container or labeling, and accompanying documentation, suspected of or determined to be counterfeit or fraudulent shall not be destroyed until its disposition is authorized by the Board and FDA.

15.08.18 An unsalable controlled substance shall be disposed of in compliance with the requirements of the drug enforcement administration and appropriate records shall be kept.

15.08.19 In the case of a drug or a device which is unsalable, records shall be kept which contain the following:

- a. The name of the drug;
- b. The strength of the drug;
- c. The dosage form if appropriate;
- d. The quantity of the drug;
- e. The name and/or NDC number of the labeler of the drug if labeled only with its generic name;
- f. If just an NDC number is used the wholesaler or manufacturer shall maintain a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable for examination by the Board for at least three years;
- g. Method of disposition of item;

- h. Date of disposition; and
 - i. Method of destruction, if applicable; and
 - j. Signature of individual destroying, if applicable, and signature of individual witnessing destruction.
- 15.09.00 Recordkeeping.
- 15.09.10 All records of receipt, distribution or other disposal of prescription drugs and/or controlled substances shall be available to the Board on request for inspection, copying, verifying or other proper use. If authorization has been granted to maintain certain records centrally at another location, these records shall be made available within two business days (forty-eight 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 Rules 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 rules and that all such controlled substances are properly accounted for.
- a. All such records, 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.
- 15.09.12 Retrievability of records. For the purposes of these Rules, 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;

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- (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.
- 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 twenty-four 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.
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- 15.09.14 Receipts.
- a. Except as provided in sections 25.5-2.5-201 through 25.5-2.5-208, C.R.S., in-state prescription drug wholesalers shall only receive prescription drugs and controlled substances from an entity that is registered by the Board. This section shall not apply to intracompany or reverse distribution transactions.
- 15.09.15 Records of receipt of prescription drugs and controlled substances shall contain the following information for each such substance received:
- a. Name of the drug;
- b. Strength of the drug;
- c. Dosage form if appropriate;
- d. Quantity received;
- e. Date received if a controlled substance;
- f. Name of the labeler of the drug if it is labeled only with its generic name;
- g. Name of the receiver;
- h. Address of the receiver;
- i. Name of the distributor that physically distributed the drug directly to the receiver;
- j. Address of the distributor where the drug was directly distributed from;
- k. Drug Enforcement Administration registration number of the distributor if a controlled substance;
- l. Drug Enforcement Administration registration number of the receiver if a controlled substance;
- m. The DEA form 222 or an electronic order form shall be completed for each schedule ii controlled substance received.
- 15.09.16 All records of receipt (including credit invoices) of prescription drugs and controlled substances shall be maintained for a period of time not less than two years from the date the drugs were received. Records of receipt (including credit invoices) of non-controlled prescription drugs need not be maintained on the premises provided that they shall be made available within 48 hours or two business days, whichever is longer, on request by the Board or its inspectors.
- 15.09.17 All records of receipt of schedule II controlled substances shall be maintained separately from all other records.
- 15.09.18 Records of receipt of schedule III, IV, and V controlled substances may be maintained with other records of receipt. However, the record shall be readily identifiable from the records of receipt of non-controlled drugs.
- 15.09.19 Distribution.

- a. A manufacturer or wholesaler as defined in Rule 15.01.00 shall furnish prescription drugs only to a person or entity licensed by the appropriate regulatory board. Before furnishing prescription drugs to a person not known to the wholesaler, the wholesaler shall affirmatively verify that the person or entity is legally authorized to receive the prescription drugs by contacting the appropriate regulatory board.
 - b. Prescription drugs furnished by a manufacturer or wholesaler shall be delivered only to a practitioner authorized by law to prescribe the drug or to an entity licensed or registered by the Board. In the case of such entities registered or licensed by the Board, drugs shall be distributed only to the registered or licensed address. The manufacturer or wholesaler may furnish prescription drugs to an authorized person or agent of the person listed on the license if the identity and authorization of the recipient is properly established and the method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person or agent.
 - c. Prescription drugs may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving agent signs, at the time of delivery, a receipt showing the type and quantity of the prescription drug received. Any discrepancy between the receipt and the type and quantity of the prescription drug actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.
- 15.09.20 Records of distribution of controlled substances and prescription drugs. An outlet which distributes prescription drugs and/or controlled substances shall record the following:
- a. The name of the drug;
 - b. The strength of the drug;
 - c. The dosage form if appropriate;
 - d. The quantity of the drug;
 - e. The name of the manufacturer or the NDC number of the drug if labeled only with its generic name;
 - f. The date of distribution;
 - g. If just an NDC number is used the wholesaler or manufacturer shall maintain a current, complete printed or typed list, which shows both the symbol and code and its complete definition. This list shall be readily retrievable for examination by the Board for at least three years;
 - h. The name and address of the distributing wholesaler;
 - i. The name and address of the receiver;
 - j. If a controlled substance is distributed, the record shall also indicate the Drug Enforcement Administration registration number of the distributing outlet and the receiver; and
 - k. A schedule II controlled substance shall only be distributed pursuant to receipt of a properly executed DEA-222 form or an electronic order.

- 15.09.21 These records of distribution shall be retained for a period of time not less than two years from the date of the distribution.
- 15.09.22 Records of distribution may be maintained electronically if the following requirements are met:
- a. The wholesaler must ensure a daily (i.e., every twenty-four hours) back up is performed for use in restoring required information in case of a system failure.
 - b. Have and maintain a complete on-line distribution file that is printable on the inspector's request, or
 - c. Have a "lock-out" feature that prevents editing of distribution information.
 - d. The Board or its inspectors must be able to inspect and review the distribution transactions of the wholesaler. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:
 - (1) Print a report of all distribution transactions for a period of time as the Board or its inspector(s) may specify. The system must be capable of retrieving and printing such a report within a limited time not to exceed two hours. Additionally, the system must be capable of retrieving and printing the information sorted according to variables which include, but are not limited to; date of distribution, drug name, strength and dosage form, and registrants receiving the distribution;
 - Or
 - (2) Provide a computer terminal and monitor for the sole use of the Board or its inspector(s) to inspect and review distribution transactions, and, if necessary, provide a person to assist the Board or its inspector(s) for a period of time not to exceed two hours in operating the system. If the outlet elects to comply with this subparagraph (2), the system must also be capable of printing the same reports described in subparagraph (1)
 - (3) It is the responsibility of the manager to ensure that all wholesale staff is aware of the requirements of subparagraphs (1) and (2). Any failure or refusal by the outlet manager and/or staff to comply with a request by the Board or its inspector(s) will be deemed to be a willful violation of these Rules.
 - e. If the outlet chooses to maintain records of distribution electronically, any reports printed upon request shall contain, as a minimum, the following information for each transaction:
 - (1) The name of the drug;
 - (2) The strength of the drug;
 - (3) The dosage form if appropriate;
 - (4) The quantity of the drug;
 - (5) The manufacturer name and/or NDC number of the drug if labeled only with its generic name;
 - (6) The date of distribution;

- (7) The name and address of the distributing outlet;
- (8) The name and address of the receiver; and
- (9) When a controlled substance is distributed, the record shall also indicate the drug enforcement registration number of the distributing outlet and the receiver.

15.09.23 Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion or other loss of any prescription drug or controlled substance to the Board or as required by the Drug Enforcement Administration or other state and/or federal agencies for prescription drugs and controlled substances.

15.09.24 Records detailing losses of prescription drugs and controlled substances shall be maintained on the premises of the registrant and shall be made readily available for inspection by the Board or its inspectors immediately upon request.

15.10.00 Policies and procedures.

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

- a. A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and is itself, an approved deviation procedure.
- b. The registrant shall have a procedure to assure that any outdated stock, or any stock with an expiration date that does not allow sufficient time for dispensing by the prescription drug outlet shall be segregated from other stock and shall be returned to the manufacturer or otherwise destroyed, and documented.
- c. A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:
 - (1) Any legal action initiated at the request of the food and drug administration or other government agency with jurisdiction:
 - (2) Voluntary action by the manufacturer to remove defective or potentially defective drugs from the market:or
 - (3) Any action undertaken to promote public health and safety by the replacing of existing merchandise with an improved product or new package design.
- d. A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security of operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency.

- e. A procedure to ensure that any outdated, misbranded, counterfeit, adulterated or unsalable prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation which shall be maintained for three years after disposition 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 and prescription drugs which have been damaged in storage or held under improper conditions.
 - g. Procedures which assure employees possess the necessary education or experience for the position they hold and the job functions they are assigned.
 - h. Procedures which assure that all prescription drugs and controlled substances are only received from entities that are registered by the Board. This section shall not apply to intracompany or reverse distribution transactions.
 - i. A procedure to ensure that drugs are distributed only to individuals or entities with authorization to possess them.
 - j. A procedure to ensure that drugs are only distributed to practitioners authorized by law to prescribe the drug or to an entity licensed or registered by the Board. In the case of such entities registered or licensed by the Board, drugs shall be distributed only to the registered or licensed address. In the event the license does not show the address, a written confirmation from the regulatory board licensing or registering the individual or entity shall be obtained.
 - k. A procedure to ensure verification of all transactions on a pedigree prior to distribution of the drug.
 - l. A procedure to ensure compliance with content, utilization, availability, and retention to certify a pedigree is furnished when distribution occurs outside of the normal distribution channel.
 - m. A procedure to ensure that staff has 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 Rule 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, either a written or oral prescription order for the drug in the course of an existing, valid veterinarian-client-patient relationship. If the order is for a Schedule III, IV or V controlled substance and it is transmitted orally, it must be immediately transcribed to writing and the practitioner's written prescription order shall be transmitted to the wholesaler within three business days of the oral order;
- b. If the order was transmitted orally, the practitioner's written prescription order shall be attached to the oral order and retained as the original 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 Drug Enforcement Administration 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 the following facilities ("outlets") to purchase, possess, store and administer drugs enumerated in this Rule 16.00.00 in a manner appropriate to the outlet as authorized by law.

- a. For the purpose of the capture, sedation or immobilization of animals prior to, and including, euthanasia of injured, sick, homeless, or unwanted pets and animals:
 - 1. an animal shelter which is duly registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation; or
 - 2. an animal control agency which is operated by a unit of government.
- b. For the purpose of administering vaccines to animals:
 - 1. an animal shelter which is duly registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation; or
 - 2. an animal control agency which is operated by a unit of government.
- c. Where the employees, agents or contractors of Colorado Division of Wildlife locations are authorized by the agency to capture or immobilize wildlife for animal control, management or research purposes, those locations are considered "animal control agencies" for purposes of section 12-280-120(17), C.R.S., and this Rule 16.00.00.
- d. All drugs purchased, possessed, stored and administered by the outlet shall be obtained from an individual or entity registered by the Board.

16.00.20 Application Procedure.

a. Original Application.

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

b. Limited License Outlet Relocation

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

c. Change of Name of Limited License Outlet.

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

d. Reinstatement of Limited License.

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

- (1) The reinstatement application that is current at the time submitted with the required fee; and
- (2) A copy of the applicant's current registration with the Drug Enforcement Administration (DEA), if applicable.

16.00.30 Security. Outlets shall maintain limited access to controlled substances and other drugs. All drugs shall be stored in locked cabinets, a safe bolted to the floor, or an equivalent secure location. Drugs shall be stored at the address registered with the Drug Enforcement Administration, or when being transported for use in the field, drugs shall be secured and in the immediate possession of the employees, agents or contractors of the outlet who are authorized by the agency to capture or immobilize wildlife.

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

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

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

a. For all limited licenses:

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

- (a) All official DEA 222 forms executed during the two years preceding the request;
- (b) All inventories of controlled substances required to be taken during the two years preceding the request;
- (c) All records of administration, receipt (invoices for drugs received and drugs credited), distribution, loss, surrender or disposal in any other manner of prescription drugs and controlled substances during the two years preceding the request;

(2) The following records shall be made available within forty-eight 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 outlet a list of the items to be retrieved. The requested records shall be made available to the inspector within forty-eight 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 outlet shall take a new inventory of all stocks of controlled substances on hand at least every two years.
- d. The following information shall be recorded on the inventory.
 - (1) The name of the drug;
 - (2) Each finished form of the drug (strength and dosage form);
 - (3) The number of units or volume of each finished form;
 - (4) All outdated controlled substances.
- e. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the other outlet shall do as follows:
 - (1) If the drug is a schedule II drug, an exact count of the contents shall be made.
 - (2) If the substance is listed in schedule III, IV, or V, an estimated count of the measure of the contents may be made, unless the container holds more than 1000 tablets or capsules, in which case an exact count of the contents must be made.
- f. All controlled substance inventories shall be retained at the outlet for at least two years from the date of such inventory.

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

- a. Animal or wildlife number, if available, or general description.
- b. Animal or wildlife weight, if available, or estimate.
- c. Amount of drug administered, and method if drug was administered for the purposes of chemical capture or control.

- d. Identification of individual administering drug.
- e. Amount of drug wasted (if applicable).
- f. Date administered.

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

16.01.00 Receipts.

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

- a. Name of the drug;
- b. Strength of the drug;
- c. Dosage form if appropriate;
- d. Quantity received;
- e. Date received if a controlled substance;
- f. Name of the labeler of the drug if it is labeled only with its generic name;
- g. Name of the distributor;
- h. Drug Enforcement Administration number of distributor if a controlled substance;
- i. The DEA form 222 or a copy of the DEA form 222 and the corresponding invoice shall be attached to each other.

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

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

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

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

16.02.00 Vaccination of animals, chemical capture and sedation of animals or wildlife for euthanasia or immobilization.

16.02.01. All limited license outlets are authorized to purchase, possess and administer vaccines for the purpose of vaccinating animals and to purchase, possess, and administer drugs commonly used for the chemical capture of animals or wildlife for control, management or research purposes or to sedate or immobilize pet animals prior to euthanasia in a manner appropriate to the outlet as authorized by law. The drugs acceptable for this use are:

- a. Acepromazine.
 - b. Ketamine.
 - c. Xylazine.
 - d. Tiletamine and Zolazepam.
 - e. Sodium Pentobarbital.
 - f. Butorphanol.
 - g. Azaperone.
 - h. Medetomidine.
 - i. Midazolam.
 - j. Haloperidol.
 - k. Nalbuphine.
 - l. Atipamezole.
 - m. Tolazoline.
 - n. Naltrexone.
 - o. Doxapram.
 - p. Yohimbine.
 - q. Diphenhydramine.
- 16.02.02. Outlets must maintain records of the receipt, distribution, loss, surrender and/or disposal of these drugs in the manner specified in Rules 16.00.50 – 16.01.50.
- 16.02.03. Outlets must demonstrate that staff are trained and capable of using the drugs as intended. For the purposes of chemical immobilization or euthanasia, 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 COLLABORATIVE PHARMACY PRACTICE.

17.00.10 Definitions.

- a. "Collaborative pharmacy practice agreement," or "collaborative practice agreement" (CPA), means a written and signed agreement or electronically approved if version and approval histories are available entered into voluntarily between one or more Colorado-licensed pharmacists and one or more physicians or advanced practice nurses licensed in this state, which statement grants authority to the pharmacist or pharmacists to provide evidence-based healthcare services to one or more patients pursuant to a specific treatment protocol delegated to a pharmacist or pharmacists by the physician or advanced practice nurse with prescriptive authority. Either party may withdraw from an agreement at any time.
 - 1. "Collaborative drug therapy management" (CDTM) is a collaborative practice agreement involving a higher level of disease complexity and/or decision making. CDTM means the review and evaluation of drug therapy regimens for patients undertaken by a pharmacist in order to provide drug therapy, monitor progress, and initiate, modify, or discontinue drug therapy. Drug therapy management may only be undertaken pursuant to an initial diagnosis made by a physician or advanced practice nurse 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 or advanced practice nurse. 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 rules.
- b. "Collaborative pharmacy practice agreement," or "collaborative practice agreement," may also mean a statewide drug therapy protocol, or "statewide protocol," developed by the Board, the Colorado Medical Board, and the Colorado State Board of Nursing in collaboration with the Colorado Department of Public Health and Environment for public healthcare services under which a pharmacist may have prescriptive authority as a practitioner.
- c. "Evidence-based healthcare service" means a healthcare service provided by a Colorado-licensed pharmacist pursuant to a collaborative practice agreement with a Colorado-licensed prescriber or prescribers which is guided by or based on current, objective, supportive scientific evidence as published in scientific literature as opposed to anecdotal observations. Evidence-based healthcare services may include:

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1. Specific services as agreed upon and defined under Rule 17.00.70(c), including but not limited to:
 - a. chronic disease management and optimization of therapeutic outcomes using medication therapies based on published clinical guidelines;
 - b. preventative services;
 - c. medication management and monitoring; and
 - d. services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of patients' symptoms, or arresting or slowing of a disease process, and include efforts to prevent, detect, and resolve medication-related problems.
 2. Prescribing and consultative services pursuant to statewide protocols as defined under Rule 17.00.50 and Appendices, including but not limited to:
 - a. Prescribing contraceptives;
 - b. Prescribing smoking cessation products; and
 - c. Prescribing human immunodeficiency virus infection prevention medications.
 - d. "Prescriber", for the purpose of this Board Rule 17.00.00, means a physician who is actively and unconditionally licensed by the Colorado Medical Board or an advanced practice registered nurse with prescriptive authority who is actively and unconditionally licensed by the Colorado State Board of Nursing.
 - e. "Protocol" means a specific written plan for a course of medical treatment containing a written set of specific directions created by a prescriber or groups of prescribers in conjunction with the participating pharmacist(s).
- 17.00.30 Pharmacist Qualifications.
- a. A pharmacist may enter into a collaborative pharmacy practice agreement with one or more prescriber if:
 1. The pharmacist holds a current license to practice in Colorado;
 2. The pharmacist is engaged in the practice of pharmacy;
 3. The pharmacist has earned a Doctor of Pharmacy degree or completed at least five (5) years of experience as a licensed pharmacist;
 4. The pharmacist agrees to devote a portion of his or her practice to collaborative pharmacy practice;
 5. There is a process in place for the physician, advanced practice registered nurse, and pharmacist to communicate and document changes to the patient's medical record; and
 6. The pharmacist carries adequate professional liability insurance in coverage of at least \$1,000,000 per incident and at least \$3,000,000 in aggregate.

7. Pharmacists practicing under CDTM protocols must also:
 - a. Meet one of the following qualifications:
 1. Proof of completion of a pharmacy residency accredited by the American Society of Health Systems Pharmacists in the specialty being practiced or;
 2. Proof of completion of one year of practice experience in pharmacotherapy, and forty hours of onsite supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or
 3. Completion of a certificate program accredited by the Accreditation Council for Pharmacy Education ("ACPE") in each area of practice, and forty hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or
 4. Completion of at least forty 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
 5. Current Board specialty certification from the Board of Pharmaceutical Societies; or
 6. In an inpatient or group model integrated closed HMO setting, all of the following criteria shall be met:
 - a. Forty hours of on-site supervised clinical practice and training in the area(s) in which the pharmacist is choosing to practice;
 - b. Protocols must be approved by the health-system's medical committee, or pharmacy and therapeutics committee; and
 - c. Documented competency in each area of practice in which the pharmacist is choosing to practice shall be maintained on site.
 - b. Licensed Colorado pharmacists practicing collaborative 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 the standard of care required for management of the specific disease. Such attestations must be on file at the site of practice. Documentation of their employment dates must be on file as proof of practice prior to August 2, 2005.
- b. This Board Rule 17.00.00 shall not prevent a pharmacist or pharmacy intern from administering vaccines and immunizations pursuant to the authorization of a physician as permitted pursuant to Board Rule 19.00.00.

17.00.50 Evidence-Based Healthcare Services Pursuant to Statewide Protocol.

- a. A process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
- b. A statewide protocol shall, at minimum, contain the following information:
 1. The nature and scope of evidence-based healthcare services appropriate for certain conditions or diagnoses, and include specific directions for the patient information to be obtained, the drug therapies to be dispensed, the specified dosage regimen, and dosage forms and route of administration which are authorized. Protocols must include criteria and specific directions pharmacists are to follow when providing evidence-based healthcare services. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol shall provide precise instruction as to what assessments are needed to be conducted and what tests are to be ordered, the criteria for ordering the assessments and tests, how the assessments and tests are to be interpreted, and what action the pharmacist is to take dependent upon the assessments and test results;
 2. The pharmacist training necessary to perform the functions set forth in the statewide protocol, which shall include the following:
 - A. A review/update of the disease or condition and the pertinent evidence base to be used by the pharmacist;
 - B. The pharmacology and mechanism of action or medications;
 - C. The relative effectiveness of various medication options;
 - D. Factors and considerations required for patient-centered medication selection;
 - E. Assessment of advantages and disadvantages of various approved medication options;
 - F. Monitoring considerations of approved medications including management of potential adverse events;
 - G. Required patient counseling considerations for approved medications; and
 - H. Identification of patients that should be referred to a primary care provider (or other appropriate resource) at any point during the protocol, or at follow up, and standardized referral process (if applicable).
 3. Specific instructions for responding to acute allergic or other adverse reactions, if applicable;

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- 4. A plan of treatment guided by or based on current, objective, supportive scientific evidence as published in scientific literature that provides generally accepted standard of care in all applicable professions;
 - 5. Specific criteria upon which a patient must not be provided care under the protocol and instead referred to the patient's primary care provider for services.
 - c. In conjunction with this Board Rule 17.00.50, the current Colorado statewide approved protocols are provided in Appendix A,B, and C.
- 17.00.70 Evidence-Based Healthcare Service Pursuant to a CPA Protocol (other than a statewide protocol) Agreement and Protocol with a Prescriber or Prescribers.
- a. Unless a statewide protocol is in place, a pharmacist shall not enter into a collaborative pharmacy practice agreement with a prescriber if the prescriber does not have an established relationship with the patient or patients who will be served by the pharmacist under the collaborative pharmacy practice agreement.
 - b. A pharmacist or prescription drug outlet shall not employ a prescriber for the sole purpose of forming a collaborative practice agreement.
 - c. Written agreements shall contain the following information:
 - 1. Participating pharmacist(s) or pharmacist group;
 - 2. Participating prescriber(s) or prescriber group;
 - 3. Protocols to be employed;
 - 4. Functions and activities the pharmacist or pharmacists will perform;
 - 5. Method, content and frequency of communication to the prescriber;
 - 6. A provision that allows the prescriber to override any action taken by the pharmacist when the prescriber deems it to be necessary;
 - 7. An effective date of the agreement, and signatures of both the participating prescriber or prescribers, pharmacist or pharmacists, or authorizing prescriber or chairperson of the authorizing group or committee; and
 - d. A protocol pursuant to an agreement between a pharmacist or pharmacists and a prescriber or prescribers shall, at minimum, contain the following information:
 - 1. The nature and scope of evidence-based healthcare services appropriate for certain conditions or diagnoses. Protocols must include criteria and directions pharmacists are to follow when providing evidence-based healthcare services. The criteria and direction may be based upon the most recent scientific literature and guidelines. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol shall provide precise instruction as to what assessments are needed to be conducted and what tests are to be ordered, and what action or process the pharmacist is to take or follow dependent upon the assessments and test results;
 - 2. Specific instructions for responding to acute allergic or other adverse reactions, if applicable;
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3. A plan of treatment guided by or based on current, objective, supportive scientific evidence as published in scientific literature that provides the generally accepted standard of care;
 4. Specific criteria upon which a patient must not be provided care under the protocol and instead referred to the patient's primary care provider for services; and
 5. An effective date of the protocol, and signatures or electronic approval of the authorized prescriber, prescribers, or authorizing individual on behalf of a group of prescribers..
- e. Additionally to all items described above, the following applies to CDTM:
1. Drug therapy management may include:
 - a. Collecting and reviewing patient drug histories;
 - b. Obtaining and checking vital signs;
 - c. Ordering and evaluating the results of laboratory tests directly, related to management of the drug therapy;
 - d. Initiate, modify, or discontinue drug therapy or therapies, when appropriate, in compliance with the protocol; and
 - e. Provision of other healthcare services as agreed upon in the protocol.
 2. CDTM protocol means a written plan for course of medical treatment containing a written set of directions created by the prescriber, groups of prescribers, hospital medical committee, pharmacist, groups of pharmacists, or a pharmacy and therapeutics committee.
 - a. Protocols must describe the nature and scope of drug therapy management appropriate to conditions or diagnosis, and include a treatment protocol and/or direct the pharmacist to follow accepted medical standards such as peer-reviewed evidence-based guidelines or treatment algorithms.
 - b. The protocols shall be signed and dated by the authorizing prescriber or chairperson of the authorizing group or committee.
 - c. Evidence-based protocols. Protocols used by prescribers 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.
- f. Agreement means a written agreement between a Colorado pharmacist and a Colorado prescriber, or a group of Colorado pharmacists and Colorado prescribers. Either party may withdraw from the agreement at any time.
- 17.00.80 Collaborative drug therapy management requirements for all practice settings.

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- a. Collaborative drug therapy management may only be conducted by a pharmacist or pharmacists pursuant to an initial diagnosis made by the prescriber or prescribers, and a written agreement, which delineates proper protocols to be used and the type of interaction that must occur between the pharmacist and prescriber.
 - b. The pharmacist(s) must ensure that the prescriber(s) with whom the pharmacist(s) is/are working is/are licensed in Colorado, in good standing, and the protocols used are within the scope of the prescriber's current license.
 - c. Prior to initiation of drug therapy management in any setting, the pharmacist or institution must inform the patient that s/he may refuse to participate in drug therapy management by the pharmacist. Inpatient or health system settings may use the patient's signature on the institution's general consent to treat as the patient's indication to participate in drug therapy management by the pharmacist.
 - d. At a minimum, the written agreement for carrying out drug therapy management between prescribers and pharmacists shall be reviewed annually, and revised, if necessary.
 - e. Pharmacists may perform by protocol all aspects of drug therapy management referenced in 17.00.10 (a)(1) provided the protocol complies with 17.00.70 and the pharmacist performing these functions is qualified as set forth in section 17.00.30 and working pursuant to a written agreement with an appropriate qualified prescriber.
 - f. Filing requirements.
 - 1. Pharmacists engaging in collaborative drug therapy management must maintain a current copy of the written agreement between the prescriber and the pharmacist or have an electronic copy of the current approved version at the location where drug therapy management is occurring. Upon requests by the Board or its inspectors, such written agreements and general authorization plans shall be submitted to the Board.
 - 2. Pharmacists practicing collaborative drug therapy management must also provide to the Board documentation of their successful completion of all qualification requirements as set forth below in 17.00.30 upon request. Copies of pharmacy degrees are not required. Copies of completion of residency or other education programs or certifications must be on file in the location of practice. Attestations from the supervising pharmacist or prescriber for clinical practice must be on file.
 - 3. Pharmacists practicing collaborative drug therapy management must have a written or electronic copy of the pertinent protocols at which they are practicing. Upon request by Board inspectors, pharmacists must produce the scientific literature upon which their protocols are derived.
- 17.01.00 Record-Keeping Requirements.
- a. Pharmacists shall maintain all records of collaborative pharmacy practice agreements, and have readily available for inspection by the Board or its inspectors at the location where evidence-based healthcare services are provided, the following:
 - 1. A current copy of the statewide protocol;
 - 2. The agreement and protocol entered into with a prescriber or prescribers;
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- 3. Documentation reflecting pharmacist educational training as specified in either the statewide protocol or protocol entered into with a prescriber or prescribers if required; and
 - b. Records pertaining to all prescriptions dispensed pursuant to this Board Rule 17.00.00 shall comply with all provisions of Board Rules 2.00.00, 3.00.00, and 11.00.00 and, if applicable, Board Rules 20.00.00, 21.00.00, and 26.00.00.
- 17.02.00 Retention of Records.
- a. All records of collaborative pharmacy agreements shall be retained for a minimum of three years from the last date of healthcare service. Such records shall be available for inspection by the patient, the prescriber or prescribers, the Board or its inspectors, 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 twenty-four hours; and
 - 4. The records are immediately available for the previous two years.
- 17.03.00 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 Health Insurance Portability and Accountability Act of 1996, and the HITECH Act of 2009, and other federal and state laws and rules.
- 17.04.00 Participation Not Mandatory
- a. No person or entity, as a condition of employment, participation on an insurance provider panel, or otherwise, shall require any prescriber to participate in or authorize collaborative practice agreements.

[Appendices A-C are located at the end of the Rules]

18.00.00 [Repealed eff. 03/17/2017]

19.00.00 ADMINISTRATION.

19.01.00 Vaccines and Immunizations.

19.01.10 Qualifications.

- a. A pharmacist certified in immunization, pharmacy intern, or pharmacy technician under the supervision of a pharmacist certified in immunization, may administer vaccines and immunizations per authorization of a physician. Administration and processing of vaccines and immunizations may occur in a Telepharmacy setting so long as the quality of supervision does not compromise the standard of care of a patient, and all other regulations are followed. A copy of the authorization shall be maintained at the prescription drug outlet. Routine childhood immunizations, as defined by the Colorado State Board of Health, shall comply with CDC guidelines.

The CDC guidelines pertaining to the immunization schedule, incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guidelines shall be provided at cost upon request. The Program Director or the Program Director's designee will provide information regarding how the incorporated guideline may be examined at any state public depository library. The guideline is also available from the organization originally issuing the guideline as follows: Centers for Disease Control and Prevention (<https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html> (reviewed February 3, 2020)). This rule does not include any later amendments or editions of the guideline.

- b. Pharmacy interns, as directly part of their normal schedule or college of pharmacy curriculum, who are trained to administer vaccines and immunizations under this Board Rule 19.01.10(c) may administer vaccines and immunizations under the direct supervision of another regulated individual as defined by Board Rule 4.00.10(l) authorized by law to administer vaccines and immunizations as part of their scope of practice.
- c. Licensees shall be considered "trained" to administer vaccines and immunizations to a person only if:
 - (1) The pharmacist or pharmacy intern has completed a pharmacy-based immunization delivery course of at least twenty hours of training, including didactic and live hands-on training that is either accredited by the Accreditation Council for Pharmacy Education or provided by an ACPE accredited school or college of pharmacy as part of obtaining a pharmacy degree.
 - (2) The pharmacy technician has completed a pharmacy based immunization administration course of at least four hours of training including didactic and live hands-on training that is accredited by the Accreditation Counsel for Pharmacy Education. Proof of completion of this training shall be posted at the pharmacist's, pharmacy intern's, or pharmacy technician's main practice location(s).

- (3) The pharmacist, pharmacy intern, or pharmacy technician 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. If the CPR certification has no expiration date, current means the certification must have been issued within the last two years. Proof of certification shall be available at licensee's main practice location.
 - (4) The vaccines are administered in accordance with CDC guidelines. The CDC guidelines pertaining to vaccine administration, incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guidelines shall be provided at cost upon request. The Program Director or the Program Director's designee will provide information regarding how the incorporated guideline may be examined at any state public depository library. The guideline is also available from the organization originally issuing the guideline as follows: Centers for Disease Control and Prevention (<https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html> (reviewed May 16, 2018)). This rule does not include any later amendments or editions of the guideline.
 - (d) 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". The CDC guideline referencing "Epidemiology and Prevention of Vaccine-Preventable Diseases," incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guideline or reference shall be provided at cost upon request. The Program Director or the Program Director's designee will provide information regarding how the incorporated guideline or reference may be examined at any state public depository library. This guideline or reference is also available on the Centers for Disease Control and Prevention's website: <https://www.cdc.gov/vaccines/pubs/pinkbook/> (13th Edition (2015)). This rule does not include any later amendments or editions of the guideline or reference.
- 19.01.20 A trained pharmacist may delegate the administration of vaccines and immunizations only to a trained pharmacy intern or pharmacy technician.
- 19.01.30 Policies and Procedures
- a. Prior to administering vaccines or immunizations, pharmacists, pharmacy interns, and pharmacy technicians must be trained in a pharmacy-based immunization course accredited as detailed in Rule 19.01.10(c).
 - 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 or immunization administered:
 - (1) The name, address, and date of birth of the patient;
 - (2) Patient responses to screening questions for indications/contraindications to the immunization or vaccine being administered;
 - (3) The date of the administration and site of injection of the immunization or vaccine;
 - (4) The name, dose, manufacturer, lot number, and expiration date of the vaccine or immunization;
 - (5) The name or identifiable initials of the administering pharmacist. If the administration is by a pharmacy intern or pharmacy technician, the initials of both the intern or pharmacy technician and supervising pharmacist;
 - (6) The signed informed consent document for each administration;
 - (7) Which vaccine information statement (VIS) was provided;
 - (8) The date the VIS was provided; and
 - (9) The name and address of the facility at which the vaccine or immunization was administered, if administered off-site.
- b. The above records shall be maintained separately from other records of the prescription drug outlet.
- c. All records required to be maintained pursuant to this Rule 19.00.00 may be maintained electronically so long as such records are maintained in a uniform and readily retrievable manner, are printable upon request of the Board or its inspectors, and can be reviewed at a viewable rate that may customarily be reviewed when otherwise in hard-copy form.

19.01.50 Off-Site Administration of Immunizations and Vaccines

- a. A prescription drug outlet may allow a licensed pharmacist to remove immunizations and vaccines from the prescription drug outlet, provided the following requirements are met:
 - (1) The prescription drug outlet maintains records which detail the removal of the immunizations and vaccines with at least the following information:
 - (a) Name, strength, dosage form, and NDC number of the immunization or vaccine removed;
 - (b) Quantity removed;
 - (c) Date removed;

- (d) Name and license number of pharmacist removing the immunization or vaccine.
- (2) The immunizations and vaccines are properly stored at compendial temperatures during transport and storage at the off-site location.
- (3) The vaccines and immunizations shall be secured during transport and storage at the off-site location so as to allow only licensed pharmacists, pharmacy interns, and pharmacy technicians affiliated with the prescription drug outlet to have access to them.
- (4) The remaining vaccines and immunizations shall be returned to the prescription drug outlet the day they were removed.
- (5) The prescription drug outlet shall maintain records detailing the vaccines and immunizations returned with at least the following information:
 - (a) Name, strength, dosage form, and NDC number of the immunizations or vaccines returned;
 - (b) Quantity returned;
 - (c) Date returned; and
 - (d) Name and license number of pharmacist returning the immunization or vaccine.
- b. All required records shall be maintained in a manner that is uniformly maintained, readily retrievable, and available for inspection for a period of three years from the date of removal off immunizations or vaccines for off-site administration.

20.00.00 CENTRAL PRESCRIPTION PROCESSING.

- 20.00.10 “Central prescription processing” means the dispensing of an order when more than one registered prescription drug outlet (pharmacy) is involved in the transaction. It is the processing by one pharmacy of a request from another pharmacy to fill or refill an order or to perform one or more dispensing functions, such as preparation, mixing, labeling, initial interpretation, and refill authorizations.
- 20.00.11 “Central prescription processing contract” means a written contract which outlines the services to be provided and the responsibilities and accountabilities of each pharmacy that is a party to the central prescription processing contract in compliance with federal and state laws and rules.
- 20.00.12 “Contract pharmacy” means a pharmacy that is a party to the same central prescription processing contract as another pharmacy performing a portion of the fulfillment of a given prescription in a shared pharmacy services arrangement.

- 20.00.20 “Initial interpretation” means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/ manual transcription and for appropriateness of therapy (e.g. known allergies, reasonable dose, duration of use, and route of administration, considering age, gender, and other patient factors; reasonable directions for use; potential or actual adverse drug reactions; drug-drug interactions; drug-food interactions; drug-disease contraindications; therapeutic duplication; proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and abuse/misuse.)
- 20.00.30 “Fulfillment” means the preparation, mixing, and placement of the ordered medication in a suitable container with appropriate labeling.
- 20.00.31 “Fulfillment pharmacy” means the pharmacy where fulfillment occurs.
- 20.00.40 “Originating pharmacy” means the pharmacy or hospital where the order is initially presented.
- 20.00.41 “Network pharmacies” means pharmacies that are under common ownership, or are parties to a central prescription processing contract, which pharmacies may perform one or more parts of the fulfillment of a given prescription.
- 20.00.43 “Shared pharmacy services” means a system that allows a common ownership or contract pharmacy to request another common ownership or contract pharmacy to conduct the initial interpretation of a prescription order or chart order. Pharmacies participating in shared pharmacy services shall comply with all provision of this Rule 20.00.00 unless otherwise specifically stated in the Rule.
- 20.00.50 The dispensing, delivery, and return of prescriptions by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription or as a wholesale distribution.
- 20.00.60 Operational Standards.
- a. A pharmacy may outsource one or more portions of the dispensing of an order to other pharmacies provided the pharmacies:
 - 1. Have the same owner or have entered into a central prescription processing contract; and
 - 2. Share a common electronic file or have appropriate technology/interface to allow access to information required to process the order; and
 - 3. Are registered with the Board as either prescription drug outlets or non-resident prescription drug outlets, depending on the pharmacy’s location, except that a nonresident pharmacy that does not physically ship, mail or deliver dispensed prescriptions directly into this state from the nonresident pharmacy location shall be exempt from the requirement of obtaining a nonresident prescription drug outlet registration pursuant to section 12-280-133(2), C.R.S. All pharmacies participating in the central prescription processing contract, or who are engaged in shared pharmacy services, must be located within the United States regardless of the requirement of a Colorado registration.
 - b. The pharmacist manager of the fulfillment pharmacy shall assure that:

1. The pharmacy maintains and uses adequate storage or shipment containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range to maintain the integrity of the medication throughout the delivery process; and
2. The filled prescriptions are shipped in containers, which are sealed in a manner as to show evidence of opening or tampering.

20.00.70 Notification to Patients.

- a. Prior to the outsourcing of any portion of the dispensing process to another pharmacy that is a contract pharmacy or pharmacy under common ownership, the pharmacy shall:
 1. Notify the patient that their prescription may be outsourced to the other pharmacy; and
 2. Give the name of the contract pharmacy or common ownership pharmacy. If the pharmacy is part of a network of pharmacies that may participate in dispensing the prescription, the patient shall be notified of this fact. Such notification may be provided through a one-time written notice to the patient or through use of a sign in the pharmacy.
- b. Prescription drug outlets in hospitals are exempt from this requirement.

20.00.80 Prescription Labeling.

- a. Prescriptions shall be labeled with all information required by section 12-280-124, C.R.S. In addition, the following shall be included on the label of any prescription dispensed via central processing:
 1. The name and address of the originating and/or fulfillment pharmacy involved in the dispensing; and
 2. The telephone number of the pharmacy that the patient or caregiver should contact regarding refills or questions about the prescription.

20.00.90 Responsibilities of Originating Pharmacy.

- a. The originating pharmacy, when transmitting a controlled substance order to a contract 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. 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.
- 20.01.10 Records.
- a. Each pharmacy shall comply with all the laws and rules relating to the maintenance of records as required by Rule 11.00.00 and be able to produce an audit trail showing all prescriptions dispensed by the pharmacy.
 - b. The originating pharmacy is responsible for retaining the order in the manner specified in Rule 11.00.00.

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

20.01.20 Policies and Procedures.

- a. A policy and procedure manual as it relates to central prescription processing or shared pharmacy services shall be maintained and complied with by all pharmacies involved in the dispensing of the prescriptions. This policy and procedure manual shall be readily available for inspection. The manual shall:
 - 1. Outline the responsibilities of each involved pharmacy;
 - 2. Include a list of the names, addresses, telephone numbers, and all license/registration numbers (including Drug Enforcement Administration registrations) of involved pharmacies;
 - 3. Delineate which pharmacy name and address appears on the prescription label.
 - 4. Include policies and procedures for:
 - i) Notifying patients that their prescription may be outsourced to another pharmacy for centralized prescription processing and the name of that pharmacy or pharmacies;
 - ii) Protecting the confidentiality and integrity of patient information;
 - iii) Dispensing prescriptions when the filled prescription has not been received from the fulfillment pharmacy;
 - iv) Maintaining appropriate records to identify the location and pharmacist responsible for all aspects of dispensing of any order;
 - v). Complying with federal and state laws and rules;
 - vi) Identifying the pharmacist responsible for each aspect of prescription preparation including, but not limited to, the drug regimen review, the initial electronic entry, any changes or modifications of the prescription record or patient profile, and the final evaluation of the completed prescription;
 - vii) Reviewing the policy and procedure at least annually. Such review shall be done by the pharmacist manager and documented as to the date of the review accompanied by the signature or electronic approval if version and approval histories are available of the pharmacist manager.

21.00.00 COMPOUNDING.

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

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

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

21.00.10 **Limitations and Record-Keeping.**

- a. No non-controlled substance preparation shall be compounded in advance in such quantity as may exceed a ninety-day supply or is necessary to accurately compound the preparation. A ninety-day supply shall be determined by the average number of dosage units dispensed or distributed of said preparation during the previous six month period. All prescription drug outlets shall comply with all applicable federal laws and rules pertaining to the compounding and dispensing of controlled substance preparations, including any federal laws or rules pertaining to compounding controlled substance preparations in anticipation of immediate need.
- b. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the final compounded product. No expired final compounded product shall be dispensed or distributed.
- c. All records required to be maintained pursuant to this Rule 21.00.00 may be maintained electronically so long as such records are maintained in a uniform and readily retrievable manner, are printable upon request of the Board or its inspectors, and can be reviewed at a viewable rate that may customarily be reviewed when otherwise in hard-copy form.

21.00.20 **Casual Sales/Distribution of Compounded Products.**

- a. 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).
- b. 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.
- c. 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
 - iii) 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.

- d. Distribution of a compounded product to a Colorado-licensed veterinarian may be for the purpose of dispensing by the receiving veterinarian only if:
 - i) The compounded product is necessary for the treatment of an animal patient's emergency medical condition; and
 - ii) As determined by the veterinarian, the veterinarian cannot access, in a timely manner, the compounded product from a prescription drug outlet or nonresident prescription drug outlet.

21.00.30 Definitions. When used in this Rule 21.00.00, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

- a. Active Pharmaceutical Ingredient (API): Chemicals, substances or other components of preparations intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in human or other animals or for use as dietary supplements.
- b. Batch (Lot): Multiple units of the same compounded preparation in a single discrete process, by the same individuals, carried out during one limited time period.
- c. Beyond-Use Date (BUD): A date after which a compounded preparation should not be stored, used or transferred and is determined from the date the preparation is compounded.
- d. Biological Safety Cabinets (BSC): A ventilated cabinet often used for preparation of hazardous drugs. These cabinets are divided into 3 general classes (Class I, Class II, Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2).
- e. Component (ingredient): Any substance which is contained in a compounded preparation.
- f. Compounding:
 - (1) The combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling or otherwise altering a drug product or bulk drug substance of one or more active ingredients with one or more other substances, or the assembling of a finished device:
 - (a) Formulated for use on or for the patient as the result of a practitioner's prescription drug order, chart order, or initiative, based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice; or
 - (b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or
 - (c) In anticipation of prescription orders based on routine, regularly-observed prescribing patterns.

- (2) Compounding does not include the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a significant difference between the compounded drug and the comparable commercially available drug product as determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products. "Significant differences" may include, but are not limited to, the removal of a dye for medical reasons (such as allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a "significant" difference to justify compounding.
- g. Containment Ventilated Enclosures (CVE): A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
- h. Designated Person: One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of non-sterile and sterile preparations
- i. Preparation or Product: A compounded drug dosage form, a compounded dietary supplement, or a finished device.
- j. Quality Assurance (QA): Set of activities used to ensure that the processes used in the preparation of non-sterile or sterile drug products lead to products that meet predetermined standards of quality.
- k. Quality Control (QC): Set of testing activities used to determine that the ingredients, components and final non-sterile or sterile drug products prepared meet pre-determined requirements with respect to strength, identity, quality, and purity.
- l. Repackaging: The subdivision or transfer of a product from one container or device to a different container or device. Repackaging does not constitute compounding, whether or not the product being repackaged was previously compounded.
- m. SOPs: Standard operating procedures.
- n. Stability: Extent to which a preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.
- o. USP/NF: The current edition of the United States Pharmacopeia/National Formulary.
- p. Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a product meeting predetermined specifications and quality attributes.
- n. Vehicle: A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended. Examples include, but are not limited to, water, syrups, elixirs, oleaginous liquids, solid and semisolid carriers, and proprietary products.

21.10.00 Compounding of Non-Sterile Preparations.

21.10.00 Scope

Compounded nonsterile preparations (CNSPs) that must comply with this rule include, but are not limited to the following dosage forms:

- a. Solid oral preparations
- b. Liquid oral preparations
- c. Rectal preparations
- d. Vaginal preparations
- e. Topical preparations (i.e., creams, gels, and ointments)
- f. Nasal and sinus preparations intended for local application (i.e., nasal sprays and nasal irrigation)
- g. Otic preparations (excluding use in perforated eardrums)

21.10.10 Policy and Procedure Manual.

- a. A manual, outlining policies and procedures encompassing all aspects of non-sterile compounding shall be available for inspection at the pharmacy. The manual shall be complied with and shall be reviewed on an annual basis. Such review shall be signed and dated or electronically approved if version and approval histories are available by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within 30 days of becoming pharmacist manager. The pharmacist manager shall ensure compliance with the manual. a.b. All personnel who conduct or oversee compounding activities must be trained in the facility's SOPs and be responsible for ensuring that they are followed.
- b. The policy and procedure manual shall address at least the following:
 - (1) Responsibility of compounding personnel;
 - (2) Verification of compounding accuracy;
 - (3) Personnel training and evaluation in compounding skills;
 - (4) Garbing Requirements and cleaning and sanitation for reusable equipment
 - (4) Environmental quality and control;
 - (5) Labeling and recordkeeping;
 - (6) Finished preparation release check;
 - (8) Storage and beyond-use dating;
 - (8)(10) Packaging and Transporting
 - (9) Adverse event reporting and recalls; and

- (10) Quality assurance and quality control programs.

21.10.20 Personnel Education, Training and Evaluation.

- a. The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel for the preparation of CNSPs. The designated person(s) must be identified in the facility's SOPs. If the compounding facility has only one person responsible for all compounding in the facility, then that person is the designated person.
- b. Pharmacy personnel who compound or have direct oversight of compounding personnel compounding CNSPs must complete training initially and every 12 months. Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs, must undergo training as required by the facility's policy and procedure manual. Documentation records of this training shall be retained for the previous 2 years.
- c. Before beginning to compound CNSPs independently or have direct oversight of compounding personnel, personnel must complete training and be able to demonstrate knowledge of principles and competency of skills for performing nonsterile manipulations as applicable to their assigned tasks in at least the following core competencies:
 - 1) Hand hygiene
 - 2) Garbing
 - 3) Cleaning and sanitizing
 - 4) Handling and transporting components and CNSPs
 - 5) Measuring and mixing
 - 6) Proper use of equipment and devices selected to compound CNSPs
 - 7) Documentation of the compounding process..
- d. Documentation of completion of training of personnel shall be retained at the pharmacy and be available for inspection.

21.10.25 Personal Hygiene and Garbing

- a. Personnel engaged in compounding must maintain appropriate hand hygiene and maintain appropriate cleanliness required for the type of compounding performed.
- b. Before entering the compounding area, compounding personnel must remove any items that are not easily cleanable and that might interfere with garbing, including:
 - (1) Remove personal outer garments (e.g., bandanas, coats, hats, and jackets)
 - (2) Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches or rings that may tear gloves)
 - (3) Remove earbuds or headphones

- c. The designated person(s) may permit accommodations provided that the quality of the environment and CNSP will not be affected. All accommodations should be documented.
- d. Personnel must perform the following procedures necessary for appropriate hand hygiene when entering the compounding area to compound:
 - (1) Wash hands with soap and water for at least 30 seconds
 - (2) Dry hands completely with disposable towels or wipers
 - (3) Don gloves
- e. Gloves must be worn for all compounding activities. Gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected.
- f. Other garb (e.g., shoe covers, head or hair covers, facial hair covers, face masks, and gowns) must be appropriate for the type of compounding performed and should be worn as needed for the protection of personnel from chemical exposures and for prevention of CNSP contamination.
- g. Garbing requirements and frequency of changing garb must be determined by the facility and documented in the policy and procedure manual.
- h. Garb should be removed when leaving the compounding area. If gowns are worn, they may be reused if not damaged or soiled. If gowns are to be reused, they must remain in the compounding area.
- i. Garb must be stored in a manner that minimizes contamination.
- j. The policy and procedure manual must describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment.

21.10.30 Environmental Quality and Controls.

- a. For entities that compound both nonsterile and sterile preparations (e.g., presterilization procedures), the respective PECs/C-PECs must be placed in separate rooms, unless those PECs/C-PECs used for nonsterile compounding are sufficiently effective that the room can continuously maintain ISO 7 classification throughout the nonsterile compounding activity. If the PECs/C-PECs used for sterile and nonsterile compounding are placed in the same room, they must be placed at least 1 meter apart and particle-generating activity must not be performed when sterile compounding is in process. The area used for non-sterile compounding should be decontaminated, cleaned and disinfected before resuming sterile compounding.
- b. The compounding area shall be designed, arranged, used, and maintained to prevent adventitious cross-contamination.
- d. The entire compounding area is to be well-lighted. Heating, ventilation, and air conditioning systems are to be controlled to avoid decomposition of chemicals.
- e. Storage areas shall provide an environment suitably controlled to ensure quality and stability of bulk chemicals and finished preparations.

- f. All components, non-freestanding equipment, and containers shall be stored off of the floor and in a manner to prevent contamination and permit inspection and cleaning of the compounding / dispensing area.
- g. Compounding areas shall be maintained in a clean, orderly, and sanitary condition.
- h. Adequate washing facilities are to be provided, including hot and cold running water, soap or detergent, and air driers or single-service towels. The sink used for cleaning of equipment used in nonsterile compounding must be emptied of all items unrelated to compounding and must be cleaned if visibly soiled before being used. The plumbing system shall be free of defects that could contribute to contamination of any compounded preparation.
- i. Purified water or better quality water, e.g., sterile water for irrigation, shall be used for compounding nonsterile preparations when formulations indicate the inclusion of water. Purified water shall also be used for rinsing equipment and utensils used in compounding.
- j. Sewage, trash, and other refuse in the compounding area are to be disposed of in a safe, sanitary, and timely manner.
- k. Special precautions shall be taken to clean equipment and compounding areas meticulously after compounding preparations that contain allergenic ingredients.

21.10.35 Cleaning and Sanitization

- a. Cleaning and sanitizing shall be completed with the following minimum frequencies:
- b. Work surfaces shall be cleaned and sanitized at the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected and between compounding CNSPs with different components.
- c. Floors shall be cleaned daily on days when compounding occurs, after spills, and when surface contamination is known or suspected.
- d. Walls and ceilings shall be cleaned when visibly soiled, after spills, and when surface contamination (e.g., from splashes) is known or suspected
- e. Storage shelving shall be cleaned every 3 months, after spills, and when surface contamination (e.g., from splashes) is known or suspected.
- f. Devices and equipment used in the compounding operation shall be cleaned and sanitized before each use and between compounding CNSPs with different components.
- g. If a CVE or BSC is used, it must be cleaned and sanitized at the beginning and end of each shift on days when compounding occurs, after spills, and when surface contamination is known or suspected . The horizontal work surface of the CVE or BSC shall be cleaned between compounding CNSPs with different components. Clean and sanitize under the work surface of a BSC monthly.
- h. Cleaning and sanitizing agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues.

- i. If cleaning and sanitizing are performed as separate steps, cleaning must be performed first.
- j. Documentation of cleaning shall be maintained and be available for inspection at the outlet for at least two years.

21.10.40 Equipment.

- a. The equipment and components used for compounding a CNSP must be suitable for the specific compounding process.
- b. Equipment shall be of suitable composition so that surfaces that contact components, in-process material, or drug products shall not be reactive, additive, or absorptive so as to alter the safety, identity, strength, quality, or purity of the drug product beyond the desired result.
- c. Equipment and devices used in the compounding or testing of compounded preparations must be inspected prior to use and, if appropriate, verified for accuracy as recommended by the manufacturer at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent.
- d. Equipment must be stored in a manner that minimizes the risk of contamination and must be located to facilitate equipment use, maintenance, and cleaning.
- e. Equipment must be cleaned in compliance with these Rules.
- f. If a CVE or BSC is used, it must be certified at least every 12 months according to manufacturer specifications.
- g. Written procedures outlining required equipment, calibration, appropriate maintenance, monitoring for proper function, controlled procedures for use of the equipment and specified time frames for these activities shall be established and followed. Results of equipment calibration and appropriate maintenance reports shall be kept on file at the outlet for at least two years from the report date. These results shall be available for inspection.

21.10.60 Components.

- a. Compounding personnel shall ascertain that ingredients for compounded products are in compliance with Rule 21.00.10(b) and are of the correct identity and appropriate quality using the following information: vendors' labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the preparation.
- b. Ingredients used in a compounded preparation shall either originate from FDA-approved sources, when available, or be USP/NF grade substances, when such sources are not available and identified on the FDA drug shortage list.
- c. If neither USP/NF grade substances nor FDA-approved substances are available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:
 - (1) Chemically Pure (CP);

- (2) Analytical Reagent (AR); or
 - (3) American Chemical Society (ACS); or
 - (4) Food Chemical Codex.
- d. For all ingredients, unless FDA-approved, the pharmacist shall establish purity and stability by obtaining a certificate of analysis from the supplier. The certificate of analysis, when applicable, shall be maintained at the prescription drug outlet for at least two years from the date of preparation.
- e. For components that do not have expiration dates assigned by the manufacturer or supplier, a pharmacist shall clearly and legibly label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the component based on the nature of the component and its degradation mechanism, the container in which it is packaged, and the storage conditions. A pharmacist shall clearly and legibly label the container with the assigned expiration date. In no event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container.
- f. A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a lot number and an expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the compounder must consider all ingredients present in the drug product relative to the intended use of a compounded preparation.
- g. Drug preparations that have been withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.
- h. Purified water or better quality, e.g., sterile water for irrigation, must be used for compounding nonsterile drug preparations when formulations indicate the inclusion of water.
- i. Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from Rule 21.10.60 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of section 12-280-131(2), C.R.S.

21.10.65 Drug Preparation Containers

- a. Pharmacy personnel shall ensure that the containers and container closures used in the packaging of compounded preparations meet all applicable USP requirements and, when available, compounding monographs.
- b. The containers and closures shall be made of suitable clean material in order not to alter the quality, strength, or purity of the compounded preparation in any way.
- c. The containers and closures shall be stored off of the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first. The containers and closures shall be stored in such a way as to permit inspection and cleaning of the compounding / dispensing area.

21.10.70 Finished Preparation Release Checks.

a. Physical Inspection

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

b. Compounding Accuracy Checks

- (1) Written procedures for double-checking compounding accuracy shall be followed for every compounded product during preparation and immediately prior to release. Outlets which compound shall have at least the following written procedures for verifying the correct identity and quality of compounded products prior to dispensing or distribution:
- (2) At the completion of compounding, before releasing and dispensing, the CNSP must be visually inspected to determine whether the physical appearance of the CNSP is as expected (e.g., color, texture, physical uniformity). Some CNSPs, as noted in their MFR, also must be visually checked for certain characteristics (e.g., emulsions must be checked for phase separation). The CNSP must be visually inspected to confirm that the CNSP and its labeling match the CR and the prescription or medication order. The inspection also must include a visual inspection of container closure integrity (e.g., checking for leakage, cracks in the container, or improper seals).

21.10.80 Storage and Beyond-Use Dating.

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

- b. In the absence of stability information that is applicable to the lowest and highest dose or concentration of a specific preparation compounded at the outlet, the following maximum beyond-use dates are to be used for non-sterile compounded preparations that are packaged in tight, light-resistant containers and as indicated:

- (1) For nonpreserved aqueous dosage forms, the beyond-use-date shall not exceed 14 days under refrigeration.
- (2) For preserved aqueous dosage forms, the beyond-use date shall not exceed 35 days at controlled room temperature or under refrigeration;
- (3) For non-aqueous oral liquids, the beyond-use-date shall not exceed 90 days at controlled room temperature or under refrigeration
- (4) For all other non-aqueous dosage forms, the beyond-use date shall not exceed 180 days at controlled room temperature or under refrigeration.
- (5) The beyond-use-date of the CNSP must not exceed the shortest remaining expiration date of any of the commercially available starting components

- (6) When there is supporting valid scientific stability information that is directly applicable to the specific preparation, the beyond-use date may be extended to that indicated in the scientific information for aqueous and non-aqueous dosage forms up to 180 days.
- (7) If the beyond-use-date of an aqueous CNSP is extended beyond the BUD indicated in Rule 21.10.80(1)(2), the CNSP must be tested for antimicrobial effectiveness or align with antimicrobial effectiveness provided by an FDA-registered facility or published in peer-reviewed literature, as long as the formulation and container closure materials are the same as those tested. Antimicrobial effectiveness testing may be performed on a low concentration and a high concentration of the active ingredient in the formulation to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing).
- (8) Any literature used to extend the beyond-use-date shall be readily retrievable and be available for inspection.

21.10.90 Master Formulation Record.

- a. For each compounded preparation, a uniform, readily retrievable formulation record shall be maintained and available for inspection for two years from the date last utilized, documenting:
 - (1) The official or assigned name, strength or activity, and dosage form of the compounded preparation;
 - (2) Calculations needed to determine and verify quantities or concentrations of components and doses of APIs, if applicable;
 - (3) All ingredients and their quantities;
 - (4) References to support the assigned BUD;
 - (5) The equipment and supplies used to compound the preparation;
 - (6) Complete instructions for preparing CSNPs that shall include:
 - (a) Order of mixing;
 - (b) Mixing temperatures or other environmental controls;
 - (c) Duration of mixing; and
 - (d) Other factors pertinent to the replication of the preparation as compounded;
 - (7) Sample labeling information which shall include, in addition to other required information:
 - (a) Generic name and quantity or concentration of each API;
 - (b) Assigned BUD;
 - (c) Storage and handling (e.g. shake well) conditions; and

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

(8) The container closure systems as used in dispensing;

(9) Packaging and storage requirements;

(10) Physical description of final product; and

(11) Procedures for quality control, if applicable.

21.11.00 Compounding Record.

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

(1) The official or assigned name and strength or activity and dosage form of the CNSP;

(2) Formulation record reference for the preparation;

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

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

(5) Total number of dosage units compounded;

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

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

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

(9) Date prepared;

(10) Assigned BUD;

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

(12) Storage conditions;

(13) Calculations, if applicable;

(14) Physical description of the final product;

(15) Results of quality control procedures, if applicable;

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

(17) Duplicate label(s) should be readily retrievable for auditing and inspection purposes as was attached to the container of the finished compounded preparation.

- 21.11.10 Labeling of Non-Sterile Compounded Preparations.
- a. Labeling of non-sterile compounded products dispensed pursuant to a prescription order or LTCF chart order shall include at least the following:
 - (1) All requirements of section 12-280-124, C.R.S.;
 - (2) Batch (lot) number, if appropriate;
 - (3) Assigned BUD;
 - (4) Storage directions when appropriate; and
 - (5) A clear statement that this product was compounded by the pharmacy, except for radiopharmaceuticals prepared from FDA-approved, commercially available kits and/or drug products.
 - b. Labeling of non-sterile compounded products dispensed pursuant to a hospital chart order shall include at least the following:
 - (1) All requirements of section 12-280-124, C.R.S.;
 - (2) Batch (lot) number, if appropriate;
 - (3) Assigned BUD; and
 - (4) Storage directions, when appropriate.
 - c. Labeling of non-sterile compounded products made in anticipation of orders shall include at least the following:
 - (1) Name and address of the outlet;
 - (2) Name and strength of the drug(s) / active ingredient(s) in the final product;
 - (3) Total quantity in package;
 - (4) Assigned BUD;
 - (5) Batch (lot) number;
 - (6) Specific route of administration;
 - (7) Storage directions, when appropriate;
 - (8) "Rx only"; and
 - (9) "This product was compounded by the pharmacy", except for radiopharmaceuticals prepared from FDA-approved, commercially available kits and/or drug products.
 - d. Labeling of non-sterile compounded products distributed within hospitals as floor stock shall include at least the following:
 - (1) Name of the outlet;

- (2) Name and strength of the drug(s);
- (3) Total quantity in package;
- (4) Quantity of active ingredient in each dosage unit;
- (5) Assigned BUD;
- (6) Batch (lot) number;
- (7) Specific route of administration; and
- (8) Storage directions, if appropriate.

21.11.20 **Quality Assurance and Quality Control. Patient Monitoring, Adverse Events Reporting, and Product Recall.**

- a. A formal, written quality assurance and quality control program must exist and address:
 - (1) Adherence to procedures
 - (2) Prevention and detection of errors and other quality problems
 - (3) Evaluation of complaints and adverse events, and
 - (4) Appropriate investigations and corrective actions
- b. The quality assurance and quality control program must be reviewed every 12 months by the designated person (s) and this review must be documented.
- c. Outlets which compound shall provide patients and other recipients of compounded preparations with a way to address their questions, complaints, and report any concerns that they may have with these preparations.
- d. The outlet shall have written policies describing specific instructions for receiving, acknowledging; and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with compounded preparations.
- e. Outlets which compound must have procedures in place to address notification about and recall of dispensed CNSP.
- f. The pharmacist manager shall report to the Board in writing significant errors related to compounded preparations such as those that result in serious personal injury or death of a patient.
- g. If a compounded preparation is believed to be defective in any way, or if the Board or Federal Food and Drug Administration makes a written request for a recall of a specific preparation, the outlet shall immediately recall any product dispensed or distributed. Any product remaining in the outlet shall be immediately quarantined and shall not be dispensed or distributed. Recall records shall include at least the following:
 - (1) Product name, strength, dosage form;
 - (2) Reason for recall;

- (3) Amount of product made;
 - (4) Date made; and
 - (5) Amount of product dispensed or distributed.
 - h. The outlet shall conduct tests, as appropriate, on the recalled product to identify reason product was defective. Results of these tests shall be retained at the outlet.
 - i. Adverse event reports and product recall records shall be retained and available for inspection at the outlet for at least two years.
- 21.11.25 CNSP Packaging and Transporting
- a. An outlet that compounds must have a policy or procedure to describe the packaging of CNSP.
 - b. If transporting CNSPs, the facility must have written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed.
- 21.20.00 Compounding of Sterile Products (CSPs).
- 21.20.10 Definitions. In addition to the definitions set forth above in Rule 21.00.30, when used in these Rules 21.20.00 *et seq.*, 21.21.00 *et seq.*, and 21.22.00 *et seq.*, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.
- a. Anteroom: An ISO Class 8 (Class 100,000) or better area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, labeling, and other activities which generate particulates. It is a transition area that provides assurance that air flows from clean to dirty areas.
 - b. Aseptic Processing: A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the packaging and the transfer of the product into the container and its closure under at least ISO Class 5 conditions.
 - c. Biological Safety Cabinet (BSC): A ventilated containment unit for personnel, product, and environmental protections having an open front with inward airflow for personnel protection, downward HEPA filtered laminar airflow for product protections, and HEPA filtered exhausted air for environmental protections.
 - d. Buffer Area: An ISO Class 7 (Class 10,000), or an ISO Class 8 for the preparation of radiopharmaceuticals, area where the primary engineering control is physically located. Activities conducted in this area include the preparation and staging of components and supplies when compounding sterile products. This area may also be referred to as a buffer or core room, buffer or cleanroom areas, buffer room area, buffer or clean area.
 - e. Class 100 Environment (ISO Class 5): An atmospheric environment which contains less than one hundred (100) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.
 - f. Class 10,000 Environment (ISO Class 7): An atmospheric environment which contains less than ten thousand (10,000) particles 0.5 microns in diameter per cubic foot of air, according to federal standards.

- g. Class 100,000 Environment (ISO Class 8): An atmospheric environment which contains less than one hundred thousand (100,000) particles 0.5 microns in diameter per cubic foot of air according to federal standards.
- h. Clean Room: A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel is not exceeded for a specified cleanliness class.
- i. Compounding Aseptic Containment Isolator (CACI): A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer process and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.
- j. Compounding Aseptic Isolator (CAI): A closed system made up of solid walls, an air-handling system, and transfer and interaction devices. The walls are constructed so as to provide surfaces that are cleanable with covering between wall junctures. The air-handling system provides HEPA filtration of inlet air. Transfer of materials is accomplished through air locks, glove rings, or ports. Transfers are designed to minimize the entry of contamination. Manipulations can take place through either glove ports or half suits. A barrier isolator is designed for compounding sterile products. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it has first passed through a HEPA filter.
- k. Compounded Sterile Products (CSPs): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.. Such products may include, but are not limited to:
 - (1) Injections, including infusions
 - (2) Irrigations for internal body cavities (i.e., any space that does not normally communicate with the environment outside of the body, such as the bladder cavity or peritoneal cavity). [NOTE—Irrigations for the mouth, rectal cavity, and sinus cavity are not required to be sterile.]
 - (3) Ophthalmic dosage forms
 - (4) Aqueous preparations for pulmonary inhalation. [NOTE—Nasal dosage forms intended for local application are not required to be sterile.]
 - (5) Baths and soaks for live organs and tissues
 - (6) Implants
- l. Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer if:

- (1) The product is prepared as a single dose for an individual patient; and
 - (2) The approved labeling includes information for the diluent, the resultant strength, the container closure system, and storage time.
- m. Critical Area: An ISO Class 5 environment.
- n. Critical Sites: Include sterile ingredients of CSPs and locations on devices and components used to prepare, package, and transfer CSPs that provide opportunity for contamination.
- o. Hazardous Drugs: A pharmaceutical product that has the capability of direct toxic action on living tissue that can result in severe leucopenia and thrombocytopenia, depression of the immune system and the alteration of a host's inflammatory response system.
- p. Disinfectant: An agent that frees from infections. It is usually a chemical agent but sometimes a physical one. It destroys disease-causing pathogens or other harmful microorganisms but may or may not kill bacterial spores. It refers to substances applied to inanimate objects.
- q. High-Efficiency Particulate Air (HEPA) filter: A filter composed of pleats of filter medium separated by rigid sheets of corrugated paper or aluminum foil that direct the flow of air forced through the filter in a uniform parallel flow. HEPA filters remove 99.97% of all particles three-tenths (0.3) microns or larger. When HEPA filters are used as a component of a horizontal or vertical-laminar-airflow workbench, an environment can be created consistent with standards for a class 100 clean room.
- r. Media-Fill Test: A test which is used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. A microbiological growth medium such as soybean-casein digest medium (SCDM) is substituted for the actual drug product to simulate admixture compounding.
- s. Multiple-Dose Container: A multiple-unit container for articles or preparations intended for parenteral administration only. These containers usually contain antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered multi-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer.
- t. Parenteral: A sterile preparation of drugs for injection through one or more layers of skin.
- u. Pharmacy Bulk Package: A container of a sterile preparation for parenteral use that contains multiple single doses. The contents of the package are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood or an equivalent clean air compounding area. Such container shall be labeled with the following:
 - (1) The name, strength and quantity of drug or base solution;
 - (2) The statement "Pharmacy Bulk Package—Not For Direct Infusion;"

- (3) Information on the proper technique to assure safe use of the product; and
- (4) A statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.
- v. Primary Engineering Control (PEC): A device or room that provides an ISO Class 5 environment for the exposure of critical sites when compounding CSPs. Such devices include, but are not limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs) and compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).
- w. Process Validation or Simulation: Microbiological simulation of an aseptic process with growth medium processed in a manner similar to the processing of the product and with the same container or closure system.
- x. Segregated Compounding Area: A part of the designated compounding / dispensing area that is a specifically designated space, either a demarcated area or room, and that is restricted to preparing Category 1 CSPs. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.
- y. Single-Dose Container: A single-unit container for articles or preparations intended for parenteral administration only. It is intended for single use and is labeled as such. Examples include, but are not limited to, prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.
- z. Sterile Pharmaceutical: A dosage form free from living microorganisms.
- aa. Sterilization: A validated process used to render a product free of viable organisms.
- bb. Sterilizing Grade Filter Membranes: Filter membranes that are documented to retain 100% of a culture of 10⁷ microorganisms of a strain of *Brevundimonas* (*Pseudomonas*) *diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22 or 0.2 micrometer porosity, depending on the manufacturer's practice.
- cc. Sterilization by Filtration: Passage of a fluid or solution through a sterilizing grade filter to produce a sterile effluent.
- dd. Terminal Sterilization: The application of a lethal process (e.g. steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterile assurance level of usually less than 10⁻⁶, or a probability of less than one in one million of a non-sterile unit.
- ee. Temperatures:
 - 1. Frozen means temperatures between twenty five degrees below zero and ten degrees below zero Celsius (-25 and -10 degrees C.) or thirteen degrees below zero and fourteen degrees Fahrenheit (-13 and 14 degrees F.).
 - 2. Refrigerated means temperatures between two and eight degrees Celsius (2 and 8 degrees C.) or thirty-six and forty-six degrees Fahrenheit (36 and 46 degrees F.).

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- 3. Room temperatures mean room temperatures between fifteen and thirty degrees Celsius (15 and 30 degrees C.) or fifty-nine and eighty-six degrees Fahrenheit (59 and 86 degrees F.).
 - ff. Unidirectional Flow: An airflow moving in a single direction, in a robust and uniform manner, and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.
- 21.20.16 Allergen Extracts as CSPs
- a. Licensed allergenic extracts are mixed and diluted to prepare prescription sets for administration to patients. A prescription set is a vial or set of vials of premixed licensed allergenic extracts for subcutaneous immunotherapy that have been diluted with an appropriate diluent for an individual patient.
 - b. Rules for compounding allergenic extracts are applicable only when:
 - 1. The compounding process involves transfer via sterile needles and syringes of conventionally manufactured sterile allergen products and appropriate conventionally manufactured sterile added substances; and
 - 2. Manipulations are limited to penetrating stoppers on vials with sterile needles and syringes and transferring sterile liquids in sterile syringes to sterile vials
 - c. Personnel Qualification for Compounding Allergenic Extract Prescription Sets.
 - 1. Before being allowed to compound, all compounding personnel must complete training and competency and be able to demonstrate knowledge and principles of sterile compounding. This includes successful completion of:
 - (a) A didactic test on sterile compounding skills
 - (b) A gloved fingertip and thumb sampling on both hands no fewer than 3 separate times after performing complete hand hygiene and garbing procedures.
 - (c) A media-fill test
 - 2. Annual personnel training must be completed and documented, including:
 - (a) A didactic test on sterile compounding skills
 - (b) A gloved fingertip and thumb sampling on both hands after performing complete hand hygiene and garbing procedures.
 - (c) A media-fill test
 - 3. Personnel who have failed competency evaluations or who have not compounded in 6 months must be re-evaluated in competencies before resuming compounding duties
 - d. Personnel Hygiene and Garbing for Compounding Allergenic Extract Prescription Sets
 - 1. Before beginning compounding of allergenic extract prescription sets, personnel must perform hand hygiene and garbing procedures
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2. The minimum garb requirements include:
 - (a) A low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gowns)
 - (b) A low-lint, disposable head cover that covers the hair and ears and, if applicable, a disposable cover for facial hair
 - (c) Face mask
 - (d) Sterile powder-free gloves
 3. Throughout the compounding process, personnel must apply sterile 70% IPA onto all surfaces of the gloves and allow them to dry thoroughly.
- e. Facilities for compounding allergenic extract prescription sets:
1. The compounding process must occur in an ISO Class 5 PEC or in a dedicated allergenic extract compounding area (AECA). The PEC or AECA used to compound allergenic extract prescription sets must be located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality. Neither a PEC nor an AECA may be located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality. The PEC or the work surfaces in the AECA must be located at least 1 m away from a sink. The impact of activities that will be conducted around or adjacent to the PEC or AECA must be considered carefully when designing such an area.
 2. If used, the PEC must be certified at least every 6 months (see 5. Certification and Recertification).
 3. If used, a visible perimeter must define the AECA.
 - a. Access to the AECA during compounding must be restricted to authorized personnel.
 - b. During compounding activities, no other activity is permitted in the AECA.
 - c. The surfaces of walls, floors, fixtures, shelving, counters, and cabinets in the AECA must be cleanable.
 - d. Carpet is not allowed in the AECA.
 - e. The surfaces in the AECA upon which the allergenic extract prescription sets are prepared must be smooth, impervious, free from cracks and crevices, and non-shedding to allow for easy cleaning and disinfecting.
 - f. Dust-collecting overhangs such as utility pipes, ledges, and windowsills, if present, must be easily cleanable.
 - g. The AECA must be designed and controlled to provide a well-lighted working environment, with temperature and humidity controls for the comfort of compounding personnel wearing the required garb.
 4. Cleaning and Disinfecting for Compounding Allergenic Extract Prescription Sets

- a. All interior surfaces of the PEC and all work surfaces of the AECA where direct compounding occurs must be cleaned and disinfected each day before compounding begins and when surface contamination is known or suspected. The horizontal work surface must be disinfected between each prescription set.
 - (1) If present, walls, doors, and door frames within the perimeter of the AECA must be cleaned and disinfected monthly and when surface contamination is known or suspected.
 - (2) Ceilings within the perimeter of the AECA must be cleaned and disinfected when visibly soiled and when surface contamination is known or suspected.
 - b. Vial stoppers on packages of conventionally manufactured sterile ingredients must be wiped with sterile 70% IPA to ensure that the critical sites are wet and allowed to dry before they are used to compound allergenic extract prescription sets.
- 6. Establishing BUDs for Allergenic Extract Prescription Sets

The BUD for the prescription set must be no later than the earliest expiration date of any allergenic extract or any diluent that is part of the prescription set, and the BUD must not exceed 1 year from the date the prescription set is mixed or diluted.
- 7. Labeling for Allergenic Extract Prescription Sets
 - a. The label of each vial of an allergenic extract prescription set must display the following prominently and understandably:
 - b. Patient name
 - c. Type and fractional dilution of each vial, with a corresponding vial number
 - d. BUD
 - e. Storage conditions
- 8. Shipping and Transporting Allergenic Extract Prescription Sets
 - a. If shipping or transporting allergenic extract prescription sets, compounding personnel must select modes of transport that are expected to deliver properly packed prescription sets in an undamaged, sterile, and stable condition. Inappropriate transport can adversely affect the quality of allergenic extract prescription sets.
 - b. When shipping or transporting allergenic extract prescription sets that require special handling, personnel must include specific handling instructions on the exterior of the container.
- 9. Documentation for Compounding Allergenic Extract Prescription Sets

- a. All facilities where allergenic extract prescription sets are prepared must have and maintain written or electronic documentation to include, but not limited to, the following:
 - i. SOPs describing all aspects of the compounding process
 - ii. Personnel training records, competency assessments, and qualification records including corrective actions for any failures
 - iii. Certification reports of the PEC, if used, including corrective actions for any failures
 - iv. Temperature logs for refrigerator(s)
 - v. CRs for individual allergenic extract prescription sets
 - vi. Information related to complaints and adverse events including corrective actions taken
 - vii. Investigations and corrective actions

21.20.20 Definitions of Sterile Compounded Products Categories

a. Immediate Use CSPs:

- (1) When all of the following conditions are met, compounding of CSPs for direct and immediate administration is not subject to the requirements for Category 1, Category 2, or Category 3 CSPs
 - (a) Aseptic techniques, processes, and procedures are followed, and written SOPs are in place to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs.
 - (b) Personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and the facility's SOPs.
 - (c) The preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs (e.g., approved labeling, stability and compatibility studies).
 - (d) The preparation involves not more than 3 different sterile products.
 - (e) Any unused starting component from a single-dose container must be discarded after preparation is complete. Single-dose containers must not be used for more than one patient.
 - (f) Administration begins within 4 h following the start of preparation. If administration has not begun within 4 h following the start of preparation, it must be promptly, appropriately, and safely discarded.

- (g) Unless directly administered by the person who prepared it or administration is witnessed by the preparer, the CSP must be labeled with the names and amounts of all active ingredients, the name or initials of the person who prepared the preparation, and the 4-h time period within which administration must be completed.
 - b. Category 1 CSPs are compounded under the least controlled environmental conditions and therefore are assigned a BUD of 12 h or less at controlled room temperature or 24 h or less when refrigerated, if compounded in accordance with all of the applicable requirements for Category 1 CSPs
 - c. Category 2 CSPs require more environmental controls and testing than Category 1 CSPs and may be assigned a BUD of greater than 12 h at controlled room temperature or more than 24 h if refrigerated, but not exceed the limits established in these Rules, if compounded in accordance with all of the applicable requirements for Category 2 CSPs
 - d. Category 3 CSPs undergo sterility testing, supplemented by endotoxin testing when applicable, and have more requirements than Category 2 CSPs for personnel qualification, use of sterile garb, use of sporicidal disinfectants, frequency of environmental monitoring, and stability determination. Category 3 CSPs may be assigned longer BUDs than those set for Category 2 CSPs but not exceeding the limits in these Rules if compounded in accordance with all applicable requirements for Category 3 CSPs.
- 21.20.23 Single-Dose Containers, Multiple-Dose Containers, and Pharmacy Bulk Packaging.
- a. Opened or needle-punctured single-dose containers shall be used within one hour if opened in worse than ISO Class 5 air quality. Single-dose containers exposed to ISO Class 5 air quality or cleaner air may be used up to twelve hours after initial puncture, as long as the labeled storage requirements during that 12-h period are maintained. Opened single-dose ampules must not be stored for any time period.
 - (1) Opened or needle-punctured single-dose containers shall be used within one hour if opened in worse than ISO Class 5 air quality. Needle-punctured single-dose containers exposed to ISO Class 5 air quality or cleaner air may be used up to twelve hours after initial puncture.
 - b. Multiple-dose containers must not be used for more than 28 days from the initial date of entering or opening, unless otherwise specified by the manufacturer.
 - c. Pharmacy bulk packages must be used according to the manufacturer's labeling. The pharmacy bulk package must be entered or punctured only in an ISO Class 5 PEC.
- 21.20.25 Radiopharmaceuticals as CSPs.
- a. Production of radiopharmaceuticals for positron emission tomography (PET) shall comply with the most current Chapter 823 of the USP/NF < Radiopharmaceuticals for Positron Emission >.
 - b. Radiopharmaceuticals shall be compounded in conformity with Rules 21.20.25(b)(1) through (4) below, Rule 12.00.00, and all other applicable sections of Rule 21.00.00.

- (1) Radiopharmaceuticals compounded from FDA-approved, commercially sterile components in closed sterile containers and with a volume of 100 ml or less for a single-dose injection or not more than 30 ml taken from a multiple-dose container shall be designated as, and conform to, the standards for low risk CSPs.
- (2) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 PEC located in an ISO Class 8 or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.
- (3) Radiopharmaceutical vials designated for multiple use, compounded with technetium-99m, exposed to an ISO Class 5 environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by the manufacturer's recommendations.
- (4) Technetium-99m/molybdenum-99 generator systems shall be stored and operated under conditions recommended by the manufacturer and applicable state and federal rules. Such generator systems shall be operated in an ISO Class 8 or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

21.20.30 Policy and Procedure Manual.

- a. A manual, outlining policies and procedures encompassing all aspects of compounding shall be available for inspection at the pharmacy. This manual shall be complied with and shall be reviewed on an annual basis. Such review shall be signed and dated or electronically approved if version and approval histories are available by the pharmacist manager. In the event the pharmacist manager changes, the new manager shall review, sign, and date the manual within thirty days of becoming pharmacist manager. The pharmacist manager shall ensure compliance with the manual.
- b. The policy and procedure manual shall address at least the following:
 - (1) Responsibility of compounding personnel, including designated person;
 - (2) Categories of compounding performed
 - (3) Development and maintenance of master formulation records;
 - (4) Initial and on-going training and competency of compounding personnel, persons with direct oversight of compounding personnel, and personnel who restock or clean sterile compounding areas;
 - (5) Garbing and Hand Hygiene, including garbing order and disinfection of re-usable equipment
 - (6) Environmental quality and control including review of temperature, humidity and pressure readings, microbiological air and surface monitoring;
 - (7) Aseptic technique, processes and procedures;
 - (8) Sterilization and depyrogenation methods

- (9) Cleaning and disinfecting activities
- (10) Calibration, maintenance, and cleaning of compounding equipment
- (11) Labeling and recordkeeping;
- (12) CSP release inspection and testing procedures;
- (13) CSP handling, storage, packaging, shipping and transport;
- (14) Adverse event reporting and recalls;
- (15) Quality assurance program; and
- (16) Quality control procedures, as appropriate.

21.20.50 Personnel Training and Evaluation:

- a. Knowledge and Core Competency of Skill
- b. Personnel who compound or have direct oversight of compounding personnel shall be initially trained and qualified by demonstrating knowledge and core competency of skill in compounding CSPs before they begin compounding or overseeing of compounding personnel.
- c. Personnel who compound or have direct oversight of compounding personnel must complete training and be able to demonstrate knowledge of principles and competency skills for performing sterile compounding initially and every 12 months in the following:
 - (1) Hand hygiene
 - (2) Garbing
 - (3) Cleaning and disinfection
 - (4) Calculations, measuring, and mixing
 - (5) Aseptic technique
 - (6) Achieving and/or maintaining sterility (and apyrogenicity if compounding with nonsterile components)
 - (7) Use of equipment
 - (8) Documentation of the compounding process (e.g., master formulation and compounding records)
 - (9) Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area
 - (10) Proper use of PECs
 - (11) Principles of movement of materials and personnel within the compounding area

- d. Competency in Garbing and Hand Hygiene
 - (1) Personnel who compound or have direct oversight of compounding personnel must complete an initial garbing competency evaluation no fewer than 3 separate times.
 - (2) After the initial garbing competency evaluations, compounding personnel must successfully complete the garbing competency at least one time every 6 months for personnel compounding Category 1 and Category 2 CSPs, and at least one time every 3 months for personnel compounding Category 3 CSPs. Personnel who have direct oversight of compounding personnel, but do not compound, must complete a garbing competency evaluation every 12 months.
 - (3) The garbing competency evaluation consists of a visual observation and gloved fingertip and thumb sampling (GFT) of both hands. The 3 completions must be in succession. Failure of any of the 3 initial garbing competency evaluations require repeat testing until successful completion of 3 in a row.
 - (4) Failure is indicated by any growth recovered from gloved fingertip and thumb sampling after garbing.
- e. Competency Testing in Aseptic Manipulation
 - (1) Personnel who compound or have direct oversight of compounding personnel must successfully complete an aseptic manipulation competency before beginning to compound.
 - (2) For personnel compounding Category 1 and Category 2 CSPs, the aseptic manipulation competency must occur initially and at least every 6 months thereafter. For personnel compounding Category 3 CSPs, the aseptic manipulation competency must occur initially and at least every 3 months thereafter. Personnel who have direct oversight of compounding personnel must complete an aseptic manipulation competency evaluation annually.
 - (3) The aseptic manipulation competency evaluation consists of a visual observation, media-fill testing, followed by a post media-fill gloved fingertip and thumb sampling on both hands, and a post media-fill surface sampling of the direct compounding area to assess aseptic technique and related practices.
 - (4) A failure in the media fill, gloved fingertip and thumb sampling, or surface sample constitutes an overall failure of the aseptic manipulation competency.
 - (i) Failure of media-fill is indicated by visible turbidity or other visual manifestations of growth in the media following the incubation period.
 - (ii) A failure in the gloved fingertip and thumb sampling post media-fill is indicated by recovery of >3 cfu as a total from both hands.
 - (iii) A failure of the surface sampling of the direct compounding area post-media fill is indicated by exceeding surface sampling action levels listed in these Rules. If action levels are exceeded for the surface sampling of the direct compounding area post media-fill, an attempt must be made to identify any microorganism recovered to a genus level.

- (iv) Personnel who fail required competencies must be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies before resuming compounding. Results of the evaluation and corrective actions must be documented, and the documentation maintained to provide a record and long-term assessment of personnel competency.
 - f. Results of all trainings, competencies, and evaluations shall be retained and be available for inspection at the outlet for at least two years.
- 21.20.60 Environmental Controls.
- a. Category 1, Category 2, and Category 3 CSPs must be compounded in an ISO Class 5 or better PEC. The PEC must be located in the buffer room of the cleanroom suite or the SCA. If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA.
 - b. A buffer room must meet at least ISO Class 7 air quality.
 - c. Anterooms providing access only to positive-pressure buffer rooms must meet at least ISO Class 8 classification. Anterooms providing access to negative-pressure buffer rooms must meet at least ISO Class 7 classification.
 - d. The clean room suite should be maintained at a temperature of 68 degrees F(20 degrees C) or cooler and a relative humidity of 60% or less.
 - e. For the compounding of non-radiopharmaceuticals, all primary engineering controls shall be placed in a buffer area that is of air quality Class 10,000 (ISO Class 7) or better. If the PEC is a CAI or a CACI that provides isolation from the room and maintains ISO Class 5 conditions during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs, then it is not required to be placed in an ISO Class 7 buffer area. For the compounding of radiopharmaceuticals, all primary engineering controls shall be placed in a buffer area that is of air quality Class 100,000 (ISO Class 8) or better.
 - f. The surfaces of the ceiling, walls, floor, fixtures, shelving, counters, and cabinets in the buffer area or clean room shall be smooth, impervious, free from cracks and crevices and non-shedding. Junctures of ceilings to walls shall be coved or caulked. There shall be no sink or floor drains in the buffer area or clean room.
 - g. An anteroom shall be physically isolated from the buffer area or clean room. In this area, supplies are uncartoned and disinfected. Hand sanitizing and gowning occurs in this area. The anteroom must have a line of demarcation to separate the clean side from the dirty side.
 - h. For CSPs prepared from one or more non-sterile components, presterilization procedures such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

- i. 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.

21.20.70 Certification and Recertification of Compounding Areas.

- a. Certification of the classified areas including the PEC must be performed initially, and recertification must be performed at least every six months and whenever the device or room is relocated or major service to the facility is performed. Certification must include:
 - (1) Airflow testing: Airflow testing is performed to determine acceptability of the air velocity, the room air exchange rate, and the room pressure differential in doorways between adjacent rooms to ensure consistent airflow and that the appropriate quality of air is maintained under dynamic operating conditions. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH must be documented on the certification report.
 - (2) HEPA filter integrity testing: HEPA filters must be leak tested at the factory and then leak tested again after installation and as part of recertification.
 - (3) Total particle count testing: Total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment.
 - (4) Dynamic airflow smoke pattern test: Smoke pattern tests must be performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).
- b. Classified areas additionally must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any PEC, or alteration in the configuration of the room that could affect airflow or air quality
 - (1) Class 100 or better clean rooms and/or primary engineering controls shall be certified by qualified operators at least every twelve 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.
 - (2) Certification that each ISO classified area is within established guidelines shall be performed no less than every twelve 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:
 - (3) 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).
 - (4) 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

- (5) 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.
- 21.20.75 Microbiological Air and Surface Monitoring
- a. The microbiological air and surface monitoring program must include 1) viable impact volumetric airborne particulate sampling and 2) surface sampling.
 - b. Microbiological air and surface monitoring must be performed initially for sterile compounding facilities prior to initiating compounding.
 - c. Microbiological air and/or surface monitoring must be conducted in all classified areas during dynamic operating conditions to confirm that the required environmental quality is maintained. In addition to the specific sampling frequencies described in this section, sampling must be performed in the following circumstances:
 - (1) In conjunction with the certification of new facilities and equipment • After any servicing of facilities or equipment
 - (2) In response to identified problems (e.g., positive growth in sterility tests of CSPs)
 - (3) In response to identified trends (e.g., repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination)
 - (4) In response to changes that could impact the sterile compounding environment (e.g., change in cleaning agents)
 - d. Volumetric active air sampling using an impaction air sampler must be conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions. For entities compounding Category 1 and Category 2 CSPs, this must be completed at least every 6 months. For entities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs. Air sampling sites must be selected in all classified areas. Sampling shall be performed at locations judged by compounding personnel to be the most prone to contamination.
 - e. All volumetric active air sampling should be conducted according to the manufacturers operating instructions for the air sampler.
 - f. Evaluate cfu counts from air samples against action levels. If levels measured during the viable air monitoring program exceed the levels for the ISO classification levels of the area sampled, the cause must be investigated, and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be dependent on the cfu count and the microorganism recovered. If action levels are exceeded, an attempt must be made to identify any microorganism recovered down to the genus level. Action levels by ISO class per 1000 liters of air are:

- (1) ISO 5 : >1 cfu
 - (2) ISO 7: >10 cfu
 - (3) ISO 8: > 100 cfu
 - g. Surface sampling must be conducted in each classified area, including each room and the interior of each ISO Class 5 PEC and pass-through chambers connecting to classified areas. For entities compounding Category 1 and Category 2 CSPs, this must be completed at least monthly. For entities compounding any Category 3 CSPs, surface sampling of all classified areas, and pass-through chambers connecting to classified areas, must be completed prior to assigning a BUD longer than the limits established in these rules, and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. Additionally, surface sampling must be conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC to prepare Category 3 CSPs, surface sampling must be conducted at least once daily at the end of compounding operations, before cleaning and disinfection occurs.
 - h. Evaluate cfu count from surface samples against action levels. If levels measured during the surface sampling exceed the levels for the ISO classification levels of the area sampled, the cause must be investigated, and corrective action must be taken. Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective. The corrective action plan must be dependent on the cfu count and the microorganism recovered. If action levels are exceeded, an attempt must be made to identify any microorganism recovered down to the genus level. Action levels by ISO class per sample are:
 - (1) ISO 5 : >3 cfu
 - (2) ISO 7: >5 cfu
 - (3) ISO 8: > 50 cfu
 - i. Records of microbiological air and surface sampling tests and corrective action plans shall be maintained and be available for inspection at the outlet for at least two years from the testing date.
 - j. 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 forty 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.
- 21.20.80 Cleaning , Disinfecting and Applying Sporidical Disinfectants and Sterile 70% IPA.
- a. Surfaces in classified areas used to prepare Category 1, Category 2, and Category 3 CSPs must be cleaned, disinfected, and have sporidical disinfectants applied according to the frequencies listed in rule 21.20.80.
 - b. The PEC and equipment inside the PEC must be cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. Sporidical disinfectant must be applied monthly for Category 1 and/or Category 2 compounding, and weekly for Category 3 compounding.

- c. Work surfaces of removable work trays of the PEC, when applicable, must be cleaned and disinfected daily on days when compounding occurs, and have a sporicidal disinfectant applied monthly. All surfaces underneath the work tray must be cleaned, disinfected, and have a sporicidal disinfectant applied monthly.
- d. The pass-through chambers, work surface(s) outside the PEC, and floors must be cleaned and disinfected daily on days when compounding occurs. Sporicidal disinfectant must be applied monthly for Category 1 and/or Category 2 compounding, and weekly for Category 3 compounding.
- e. Walls, ceilings, doors, door frames, equipment outside the PEC(s) and storage shelving and bins shall be cleaned, disinfected and have a sporicidal disinfectant applied monthly.
- f. After the disinfectant or sporicidal disinfectant is applied to the surface, the agent must be allowed to dwell for the minimum contact time specified by the manufacturer.
- g. Cleaning, disinfecting and sporicidal agents used within the PEC must be sterile. When diluting concentrated cleaning and disinfecting agents for use in the PEC, sterile water must be used.
- h. All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads) with the exception of tool handles and holders must be low lint. In addition, cleaning and disinfecting supplies used in the PEC must be sterile with the exception of tool handles and holders, which must be cleaned and disinfected prior to use in a PEC. Wipers, sponges, pads, and mop heads should be disposable. If disposable cleaning supplies are used, they must be discarded after each cleaning activity. Reusable cleaning tools must be made of cleanable materials (e.g., handles should not be made of wood or any other porous material) and must be cleaned and disinfected before and after each use. Reusable cleaning tools must be dedicated for use in the classified areas or SCA and must not be removed from these areas except for disposal.

21.20.90 Personal Hygiene and Garbing.

- a. All personnel entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must take appropriate steps to minimize microbial contamination of the environment and of the CSPs, including hand hygiene, garbing, and consideration of needed materials to be brought into the compounding area
- b. Individuals that may have a higher risk of contaminating the CSP and the environment (e.g., personnel with rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections) must report these conditions to the designated person(s). The designated person(s) is responsible for evaluating whether these individuals should be excluded from working in compounding areas before their conditions have resolved because of the risk of contaminating the CSPs and the environment.
- c. Food (including mints, gum, etc.) and drinks must not enter anterooms, buffer rooms, or segregated compounding areas.
- d. Before entering a compounding area, individuals must remove any items that are not easily cleanable or are not necessary for compounding. At a minimum, individuals must:
 - (1) Remove personal outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests)
 - (2) Remove all cosmetics because they shed flakes and particles

- (3) Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing (e.g., the fit of gloves, cuffs of sleeves, and eye protection) or otherwise increase the risk of contamination of the CSP. Cover any jewelry that cannot be removed.
 - (4) Not wear earbuds or headphones
 - (5) Not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area
 - (6) Keep nails clean and neatly trimmed to minimize particle shedding and avoid glove punctures. Nail products (e.g., polish, artificial nails, and extenders) must not be worn
 - (7) Wipe eyeglasses, if worn
- e. The designated person(s) may permit accommodations to personnel preparation as long as the quality of the CSP and environment will not be affected. Accommodations must be documented.
- f. Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must wash hands and forearms up to the elbows with soap and water before initiating compounding activities. Brushes must not be used for hand hygiene. Hand dryers must not be used. To minimize the risk of extrinsic contamination, disposable soap containers must not be refilled or topped off.
- g. The order of hand washing and garbing must be determined by the facility and documented in the facility's SOPs. Hands must be sanitized with alcohol-based hand rub before donning sterile gloves. Sterile gloves must be donned in a classified room or SCA.
- h. Any person entering a compounding area where Category 1, Category 2, or Category 3 CSPs are prepared must be properly garbed. Garb must be donned and doffed in an order that reduces the risk of contamination. The required garb, manner of storage, and order of garbing must be determined by the facility and documented in the facility's SOPs.
- i. When preparing Category 2 or Category 3 CSPs, all garb should be donned in a classified area before entering the buffer room. If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb. Skin must not be exposed inside the ISO Class 5 PEC (e.g., gloves must not be donned or doffed inside the ISO Class 5 PEC exposing bare hands).
- j. The minimum garbing requirements for preparing Category 1 and Category 2 CSPs include the following:
 - (1) Low-lint garment with sleeves that fit snugly around the wrists and an enclosed neck (e.g., gown or coverall)
 - (2) Low-lint covers for shoes
 - (3) Low-lint cover for head that covers the hair and ears, and if applicable, cover for facial hair
 - (4) Low-lint face mask • Sterile powder-free gloves

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- (5) If using a RABS (i.e., a CAI or CACI), disposable gloves should be worn inside the gloves attached to the RABS sleeves. Sterile gloves must be worn over the gloves attached to the RABS sleeve
 - k. Garb must be replaced immediately if it becomes visibly soiled or if its integrity is compromised. Gowns and other garb must be stored in a manner that minimizes contamination (e.g., away from sinks to avoid splashing). If compounding Category 1 and Category 2 CSPs, gowns may be reused within the same shift by the same person if the gown is maintained in a classified area or adjacent to, or within, the SCA in a manner that prevents contamination.
 - l. When personnel exit the compounding area, garb, except for gowns, cannot be reused and must be discarded or laundered before reuse. The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.
 - m. If the facility compounds Category 3 CSPs, additional garbing requirements must be continuously met in the buffer room in which Category 3 CSPs are prepared. The following additional garbing requirements must be followed in the buffer room where Category 3 CSPs are prepared for all personnel regardless of whether Category 3 CSPs are compounded on a given day:
 - (1) Do not allow any exposed skin in the buffer room (i.e., face and neck must be covered).
 - (2) All low-lint outer garb must be sterile, including the use of sterile sleeves over gauntlet sleeves when a RABS is used.
 - (3) Disposable garbing items must not be reused, and laundered garb must not be reused without being laundered and resterilized with a validated cycle.
 - (4) The facility's SOPs must describe disinfection procedures for reusing goggles, respirators, and other reusable equipment
 - n. Gloves must be sterile and powder free. Application of sterile 70% IPA to gloves must occur immediately before compounding and regularly throughout the compounding process. All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected
 - o. The preceding subsections under 21.20.90 (d),(e), and (f) shall not apply if a public health order is in effect and consequently availability of required garbing equipment is not available or in short supply. Compounding personnel shall use compounding best practices outlined in a respective public health order, if applicable.
- 21.21.10 Components.
- a. Compounding personnel shall ascertain that ingredients for CSPs are in compliance with these Rules and are of the correct identity and appropriate quality using the following information: vendors' labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions. No expired components may be used in compounding. No component may be used which will expire prior to the beyond-use date of the finished CSP.
 - b. Ingredients used in a compounded preparation shall either originate from FDA-approved sources, when available, or be USP/NF grade substances when such sources are not available and identified on the FDA drug shortage list.
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- c. If neither USP/NF grade substances nor FDA-approved substances are available, or when food, cosmetics, or other substances are, or must be used, the substance shall be of a chemical grade in one of the following categories:
 - (1) Chemically Pure (CP);
 - (2) Analytical Reagent (AR); or
 - (3) American Chemical Society (ACS); or
 - (4) Food Chemical Codex.
- d. For all ingredients, unless FDA-approved, the pharmacist shall establish purity and stability by obtaining a certificate of analysis from the supplier. The certificate of analysis, when applicable, shall be maintained at the prescription drug outlet for at least two years from the date of preparation.
- e. A manufactured drug product may be a source of active ingredient. Only manufactured drugs from containers labeled with a lot number and an expiration date are acceptable as a potential source of active ingredients. When compounding with manufactured drug products, the compounder must consider all ingredients present in the drug product relative to the intended use of a compounded preparation.
- f. Drug preparations that have been withdrawn or removed from the market for safety reasons shall not be compounded. Such preparations may be compounded exclusively for veterinary use provided no documentation exists which indicates that the preparation is unsafe for such use.
- g. Sterile ingredients and components:
 - (1) A written procedure for physical inspection of ingredients and components prior to compounding shall be followed.
- h. Non-sterile ingredients and components:
 - (1) When APIs are used:
 - (i) Must comply with the criteria in the USP–NF monograph, if one exists
 - (ii) Must have a COA that includes the specifications (e.g., compendial requirements for quality) and that test results for the component show that the API meets expected quality
 - (iii) Must be manufactured by an FDA-registered facility
 - (2) For all components other than APIs:
 - (i) Must comply with the criteria in the USP–NF monograph, if one exists
 - (ii) Must be accompanied by documentation (e.g., COA, labeling) that includes the specifications and test results and shows that the component meets the specifications

- (iii) If non-USP or non-NF active ingredients, added substances, or excipients are utilized, a certificate of analysis from the supplier of the ingredient shall be maintained at the prescription drug outlet for at least two from the date of preparation.
- (3) Component Receipt:
 - (i) Upon receipt of each lot of a component, the external packaging must be examined for evidence of deterioration and other aspects of unacceptable quality. Facility personnel must verify the labeling and condition of the component [e.g., whether the outer packaging is damaged and whether temperature-sensing indicators show that the component has been exposed to excessive temperature(s)].
 - (ii) Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether the date of receipt by the compounding facility must be clearly marked on each API or added substance package that lacks a vendor expiration date. Packages of components (i.e., API and added substances) that lack a vendor's expiration date must be assigned a conservative expiration date, not to exceed 1 year after receipt by the compounding facility other lots have the same defect.
- (4) Component evaluation before use:
 - (i) Compounding personnel must ascertain before use that components for CSPs are of the correct identity, appropriate quality, within expiry date and have been stored under appropriate conditions.
 - (ii) All components must be reinspected before use. All packages must be reinspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aroma, and/or texture of the contents that might have occurred during storage. Sterile container closures must be visually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.
 - (iii) Any component found to be of unacceptable quality must be promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal. Any other lots of that component from that vendor must be examined to determine whether other lots have the same defect
- (5) Component handling and storage:
 - (i) All components must be handled and stored in a manner that prevents contamination, mix-ups, and deterioration.
 - (ii) Components must be stored in closed containers under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers.

- (iii) Personnel must monitor temperature in the area(s) where components are stored either manually at least once daily on days that the facility is open or by a continuous temperature recording device to determine whether the temperature remains within the appropriate range. The results of the temperature readings must be documented on a temperature log or stored in the continuous recording device and must be retrievable. All monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer

(6) USE OF CSPs AS COMPONENTS

- (i) Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing. Multiple-dose CSPs must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). After a multiple-dose CSP is initially entered or punctured, the multiple-dose CSP must not be used for longer than the assigned BUD or 28 days, whichever is shorter. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP.
 - (ii) When a compounded single-dose CSP or CSP stock solution is used as a component to compound additional CSPs, the original compounded single-dose CSP or CSP stock solution must be entered or punctured in ISO Class 5 or cleaner air and must be stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). The component CSP may be used for sterile compounding for up to 12 h or its assigned BUD, whichever is shorter, and any remainder must be discarded. This time limit for entering or puncturing is not intended to restrict the BUD of the final CSP.
- i. Any ingredient regulated by the FDA through an Investigational Review Board (IRB) is exempt from Rule 21.21.10 provided the research requirements for the receipt of the ingredient is followed and meets the requirements of section 12-280-131(2), C.R.S.

21.21.20 STERILIZATION AND DEPYROGENATION

- a. sterilization method used must sterilize the CSP without degrading its physical and chemical stability
- b. A description of the terminal sterilization and depyrogenation process, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs) must be included in the facility's SOPs
- c. SOPs must include training and competency of personnel on all sterilization methods and equipment used by the facility. In addition, the SOPs must include a schedule and method for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment

21.21.21 Equipment.

- a. Written procedures outlining required equipment, calibration, appropriate maintenance, monitoring for proper function, controlled procedures for use of the equipment and specified time frames for these activities shall be established and followed. Results of equipment calibration and appropriate maintenance reports shall be kept on file at the outlet for at least two years from the report date and shall be available for inspection.
- b. Accuracy assessments of automated compounding devices (ACD) shall be conducted daily for each day used. At routine intervals, the pharmacist manager, or his or her designee, shall review these assessments to avoid potentially clinically significant cumulative errors over time. These assessments shall be documented and be maintained and available for inspection at the outlet for at least two years.
- c. All equipment and Supplies (e.g., beakers, utensils, needles, syringes, filters, and tubing sets) should be of suitable composition such that the surfaces that contact components are not reactive or sorptive. Supplies in direct contact with the CSP must be sterile and depyrogenated.

21.21.30 CSP Release Checks and Tests.

a. Physical Inspection

- (1) Finished CSPs shall be individually inspected after compounding pursuant to written procedures. Immediately after compounding, and prior to dispensing or distribution, each product shall be inspected for evidence of particulates or other foreign matter, container-closure integrity, precipitation, cloudiness, and any other apparent visual defect. Defective product shall be segregated from other product and shall not be dispensed or distributed.

b. Compounding Accuracy Checks.

- (1) Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. Outlets which compound CSPs shall have at least the following written procedures for verifying the correct identity and quality of CSPs prior to dispensing or distribution:
 - (a) Verification of label for accuracy;
 - (b) Correct identities, purities, and amounts of ingredients have been used; and
 - (c) Correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained.

c. Sterility Testing.

- (1) Category 1 CSPs do not require sterility testing. Sterility testing shall be done on Category 2 CSPs assigned a BUD that requires sterility testing and all Category 3 CSPs:
 - (a) If sterility testing is performed, the minimum quantity of each container to be tested for each media is specified in <71>

- (b) The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units
 - (c) If the number of CSPs to be compounded in a single batch is less than the number of CSPs needed for testing as specified in <71>, additional units must be compounded to perform sterility testing as follows:
 - (i) If 1–39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number. For example:
 - (ii) If 1 CSP is compounded, 10% of 1 rounded up to the next whole number would indicate that 1 additional CSP must be prepared for sterility testing
 - (iii) If 39 CSPs are compounded, 10% of 39 rounded up to the next whole number would indicate that 4 additional CSPs must be prepared for sterility testing
 - (iv) If more than 40 CSPs are prepared in a single batch, the sample sizes specified in <71> must be used.
 - (v) If sterility testing is performed according to <71>, the Method Suitability Test from that chapter must be performed to ensure that contamination can be recovered. If performing sterility testing according to <71>, the Membrane Filtration method from that chapter is the method of choice when the CSP formulation permits. The preferred alternative is the <71>, Test for Sterility of the Product to Be Examined, Direct Inoculation of the Culture Medium method. If an alternative method is used for sterility testing, the method must be validated and demonstrated to be suitable for that CSP formulation.
 - (d) Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented product.
- (2) When a Category 3 CSP is dispensed or distributed before receiving the results of the sterility test, there shall be a written procedure requiring daily observation of the incubating test specimens and requiring an immediate recall if there is any evidence of microbial growth. In addition, the patient and the practitioner of the patient to whom a potentially contaminated CSP was administered shall be notified of the potential risk. Positive sterility results shall prompt a rapid and systematic investigation of aseptic technique, environmental and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

- d. Bacterial Endotoxin (Pyrogen) Testing.
- (1) Category 1 injectable CSPs do not require testing for bacterial endotoxins. Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing and Category 3 injectable CSPs compounded from one or more nonsterile component(s) must be tested to ensure that they do not contain excessive bacterial endotoxins (<85>):
- Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that does not require sterility testing should be tested for bacterial endotoxins. In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula source, the CSP must not exceed the endotoxin limit calculated as described in <85> for the appropriate route of administration for humans. CSPs for nonhuman species must not exceed the endotoxin limit calculated as described in <85> based on the largest recommended dose and weight (or average weight for more than a single animal) of the target animal species unless a different limit is scientifically supported. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs
- (2) The endotoxin test shall be compliant with the most current USP/NF Chapter 85 < Bacterial Endotoxins Test >. In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP must not exceed the amount of USP/NF Endotoxin Units (EU per hour per kg of body weight) specified for the route of administration.

21.21.40 Storage and Beyond-Use Dating.

- a. The temperature of drug storage areas of CSPs shall be monitored and recorded daily, either manually or electronically. Temperature records shall be maintained and be available for inspection for at least two years.
- b. Finished CSPs that are not immediately dispensed or administered shall be refrigerated or frozen unless their chemical and physical stability are known to be adversely affected by cold or freezing temperatures.
- c. Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (i.e., the BUD). The BUD is determined from the date and time that preparation of the CSP is initiated. The BUD is not intended to limit the time during which the CSP is administered (e.g., infused).
- c. In the absence of sterility testing for each compounded batch compliant with the most current USP/NF Chapter 71 <Sterility Tests>, the beyond-use date (before administration) shall not exceed the following:
- (1) Category 1 CSPs:
- (i) Room temperature: No more than 12 hours
- (ii) Refrigerated temperature: No more than 24 hours
- (iii) Frozen: Not applicable
- (2) Category 2 CSPs aseptically processed; no sterility testing; prepared from one or more nonsterile ingredients:

- (i) Room temperature: 1 day
 - (ii) Refrigerated temperature: 4 days
 - (iii) Frozen: 45 days
- (3) Category 2 CSPs; aseptically processed; no sterility testing; prepared from only sterile ingredients:
 - (i) Room temperature: 4 day
 - (ii) Refrigerated temperature: 10 days
 - (iii) Frozen: 45 days
- (4) Category 2 CSPs; aseptically processed; sterility testing performed and passed:
 - (i) Room temperature: 30 day
 - (ii) Refrigerated temperature: 45 days
 - (iii) Frozen: 60 days
- (5) Category 2 CSPs; terminally sterilized; no sterility testing:
 - (i) Room temperature: 14 days
 - (ii) Refrigerated temperature: 28 days
 - (iii) Frozen: No more than 45 days
- (6) Category 2 CSPs; terminally sterilized; sterility testing performed and passed:
 - (i) Room temperature: 45 days
 - (ii) Refrigerated temperature: 60 days
 - (ii) Frozen: No more than 90 days
- (7) Category 3 CSPs; aseptically processed; sterility testing performed and passed:
 - (i) Room temperature: 60 days
 - (ii) Refrigerated temperature: 90 days
 - (iii) Frozen: 120 days
- (8) Category 3 CSPs; terminally sterilized; sterility testing performed and passed:
 - (i) Room temperature: 90 day
 - (ii) Refrigerated temperature: 120 days
 - (iii) Frozen: 180 days

- d. Proprietary bag and vial systems:
 - (1) Docking and activation of proprietary bag and vial systems in accordance with the manufacturer's labeling for immediate administration to an individual patient is not considered compounding and may be performed outside of an ISO Class 5 environment.
 - (2) Docking of the proprietary bag and vial systems for future activation and administration is considered compounding and must be performed in an ISO Class 5 environment
 - (3) Beyond-use dates (BUDs) for proprietary bag and vial systems must not be longer than those specified in the manufacturer's labeling

21.21.50 Master Formulation Record.

- a. For each CSP, a uniform, readily retrievable master formulation record shall be maintained and available for inspection for two years from the date last utilized, documenting:
 - (1) The name, strength, or activity, and dosage form of the compounded preparation;
 - (2) All ingredients and their quantities;
 - (3) Type and size of container closure system(s);
 - (4) Complete instructions for preparing the CSP, including equipment, supplies, a description of the compounding steps, and any special precautions;
 - (5) Physical description of the final CSP;
 - (6) BUD and storage requirements;
 - (7) Reference source to support the stability of the CSP;
 - (8) Quality control (QC) procedures (e.g., pH testing, filter integrity testing); and
 - (9) Other information as needed to describe the compounding process and ensure repeatability (e.g., adjusting pH and tonicity; sterilization method, such as steam, dry heat, irradiation, or filter).

21.21.60 Compounding Record.

- a. For each CSP prepared, a compounding record shall be maintained and available for inspection for two years on the original order, or on a separate, uniform, readily retrievable record documenting the following:
 - (1) Name, strength or activity, and dosage form of the CSP
 - (2) Date and time of preparation of the CSP
 - (3) Assigned internal identification number (e.g., prescription, order, or lot number)
 - (4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP

- (5) Name of each component
- (6) Vendor, lot number, and expiration date for each component
- (7) Weight or volume of each component
- (8) Strength or activity of each component
- (9) Total quantity compounded
- (10) Final yield (e.g., quantity, containers, number of units)
- (11) Assigned BUD and storage requirements
- (12) Results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing;
- (13) MFR reference for the CSP, if applicable
- (14) Calculations made to determine and verify quantities and/or concentrations of component, if applicable.

21.21.70 Labeling of CSPs.

a. Labeling of CSPs made in anticipation of orders shall include at least the following:

- (1) All requirements of section 12-280-124, C.R.S.;
- (2) Batch (lot) number, if appropriate;
- (3) Beyond-use date;
- (4) If for parenteral administration, the following shall be included:
 - (a) Name of base solution; and
 - (b) Name and amounts of drugs added.
- (5) Storage directions; and
- (6) A clear statement that this product was compounded by the pharmacy, except for radiopharmaceuticals prepared from FDA-approved, commercially available kits and/or drug products.

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

- (1) All requirements of section 12-280-124, C.R.S.;
- (2) Batch (lot) number, if appropriate;
- (3) Beyond-use date;
- (4) If for parenteral administration, the following shall be included;

- (a) Name of base solution; and
 - (b) Name and amounts of drugs added; and
 - (5) Storage directions.
- c. Labeling of CSPs distributed to practitioners, other prescription drug outlets, or other outlets allowed by law shall include at least the following:
 - (1) Name of the outlet;
 - (2) Name and strength of the drug(s);
 - (3) Total quantity in package;
 - (4) Quantity of active ingredient in each dosage unit;
 - (5) Beyond-use date;
 - (6) Batch (lot) number;
 - (7) Specific route of administration;
 - (8) Storage directions;
 - (9) "Rx only"; and
 - (10) A clear statement that this product was compounded by the pharmacy, except for radiopharmaceuticals prepared from FDA-approved, commercially available kits and/or drug products.
- d. Labeling of CSPs distributed within hospitals as floor stock shall include at least the following:
 - (1) Name of the outlet;
 - (2) Name and strength of the drug(s);
 - (3) Total quantity in package;
 - (4) Quantity of active ingredient in each dosage unit;
 - (5) Beyond-use date;
 - (6) Batch (lot) number;
 - (7) Specific route of administration; and
 - (8) Storage directions.

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- 21.21.80 CSP HANDLING, STORAGE, PACKAGING, SHIPPING, AND TRANSPORT:
- a. Processes and techniques for handling, storing, packaging, and transporting CSPs must be outlined in the facility's SOPs. Personnel who will be handling, storing, packaging, and transporting CSPs within the facility must be trained in accordance with the relevant SOPs, and the training must be documented.
 - b. CSPs must be handled in a manner that maintains CSP quality and packaging integrity. Conditions of storage areas must be monitored daily. Personnel must monitor conditions in the storage areas. When it is known that a CSP has been exposed to temperatures either below or above the storage temperature limits for the CSP, a designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the CSP is expected to retain its integrity or quality. If this cannot be determined, it must be discarded
 - c. Compounding personnel must select appropriate shipping containers and modes of transport that are expected to deliver properly packed CSPs in an undamaged, sterile, and stable condition..
- 21.21.90 Patient Monitoring, Adverse Events Reporting, and Product Recall.
- a. Outlets which compound CSPs shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.
 - b. The outlet shall have written policies describing specific instructions for receiving, acknowledging, and dating receipts; and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs.
 - c. The pharmacist manager shall report to the Board in writing significant errors related to compounded CSPs such as those that result in serious personal injury or death of a patient.
 - d. If a CSP is believed to be defective in any way, or if the Board or Federal Food and Drug Administration makes a written request for a recall of a specific preparation, the outlet shall immediately recall any product dispensed or distributed. Any product remaining in the outlet shall be immediately quarantined and shall not be dispensed or distributed. Recall records shall include at least the following:
 - (1) Product name, strength, dosage form;
 - (2) Reason for recall;
 - (3) Amount of product made;
 - (4) Date made; and
 - (5) Amount of product dispensed or distributed.
 - e. The outlet shall conduct tests, as appropriate, on the recalled product to identify the reason the product was defective. Results of these tests shall be maintained at the outlet for at least two years.
 - f. Adverse event reports and product recall records shall be retained and be available for inspection at the outlet for at least two years.
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21.22.00 Quality Assurance Program.

- a. Outlets that make CSPs shall have a formal written quality assurance (QA) program which shall provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes regarding the compounding of sterile products.
- b. At a minimum, the written QA program shall include the following:
 - (1) Consideration of all aspects of the preparation, dispensing, and distribution of products, including environmental testing, work area cleaning effectiveness, validation results, etc;
 - (2) Describe specific monitoring and evaluation activities;
 - (3) Specification of how results are to be reported and evaluated;
 - (4) Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded;
 - (5) Recall procedures; and
 - (5) Delineation of the individuals responsible for each aspect of the QA program.

21.22.10 Hazardous Drug Preparation.

- a. Hazardous drugs shall be compounded in a vertical flow, Class II biological safety cabinet (BSC) or CACI. Such BSC or CACI shall be placed in an ISO Class 7 area that is physically separated from other preparation areas and is negative pressure to adjacent positive pressure anteroom. If used for other products, the cabinet must be thoroughly cleaned;
- b. Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using closed-system vial transfer devices (CSTDs). PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI;
- c. Appropriate safety and containment techniques for compounding hazardous drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products;
- d. Appropriate disposal containers for used needles, syringes, and if applicable, hazardous waste from the preparation of chemotherapy agents and infectious waste from patients' homes. Disposal of hazardous waste shall comply with all applicable local, state and federal requirements;
- e. Written procedures for handling major and minor spills and generated waste of hazardous agents must be developed and must be included in the policy and procedure manual; and
- f. Prepared doses of hazardous drugs must be labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

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

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

22.00.00 [Repealed eff. 07/15/2010]

23.00.00 ELECTRONIC PRESCRIPTION MONITORING PROGRAM.

23.00.10 Definitions:

- a. "Bona fide investigation," for purposes of an investigation of an individual prescriber under investigation by a state regulatory board, means:
 - 1. Any investigation conducted by any state regulatory board within the Colorado Division of Professions and Occupations, or the Director of the Colorado Division of Professions and Occupations and
 - 2. Investigations pertaining to matters which are the subject of a complaint or notice of charges pending in the Office of Administrative Courts so long as the information obtained from the PDMP is made available by the state regulatory board to the respondent in the pending case.
- b. "Bona fide research or education" means research conducted by qualified entities whose recognized primary purpose is scientific inquiry; the results of which would likely contribute to the basic knowledge of prescribing practitioners, dispensing pharmacists, or entities for the purpose of curtailing substance abuse of consumers. The Board shall determine in its discretion on a case-by-case basis whether an individual or entity seeking access to the PDMP pursuant to section 12-280-404(6), C.R.S., constitutes "bona fide research or education" conducted by qualified personnel for purposes of satisfying the statutory limitations therein.
- c. "Client", as it pertains to a licensed veterinarian's use of the PDMP, means the patient's owner, the owner's agent, or a person responsible for the patient.
- d. "Clinical patient care services" means pharmaceutical care provided in a clinical setting. The pharmacist providing clinical patient care services must be working closely with the physician/prescriber responsible for the patient's care. "Clinical patient care services" do not include monitoring previously dispensed prescriptions for any purpose in the absence of a current assessment of a patient whether in a clinical setting or not.
- e. "Law Enforcement Official" means any of the following:
 - 1. Sheriff;
 - 2. Undersheriff;
 - 3. Certified deputy sheriff;
 - 4. Police Officer;

5. Southern Ute Police Officer;
 6. Ute Mountain Ute police officer;
 7. Town Marshall;
 8. CBI director and agents;
 9. Colorado state patrol officer;
 10. Colorado attorney general and any entity designated as “peace officers” by the Attorney General or acting on behalf of a state agency;
 11. Attorney general criminal investigator;
 12. District attorney and all assistants, deputies, etc. statutorily defined as “peace officers;”
 13. District Attorney Chief investigator and investigators;
 14. Police administrator and police officers employed by the Colorado State Hospital in Pueblo; and
 15. Federal special agents.
- f. “Legitimate program to monitor a patient’s controlled substance abuse” means a program in which prescribers actively monitor a patient’s controlled substance use. Such programs shall only involve patients in pain management or other controlled substance management programs. Such programs shall actively monitor the patient’s controlled substance usage by means of urine or other drug screens in addition to the use of the PDMP. The patient must be informed in writing that his/her controlled substance usage is being actively screened by various methods, including review of the PDMP.
- g. “Mistreat”, as it pertains to a licensed veterinarian’s use of the PDMP, means every act or omission which causes or unreasonably permits the continuation of unnecessary or unjustifiable pain or suffering.
- h. “Patient”, as it pertains to a licensed veterinarian’s use of the PDMP, means an animal that is examined or treated by a licensed veterinarian and includes herds, flocks, litters and other groups of animals.
- i. “PDMP” means the Electronic Prescription Drug Monitoring Program.
- j. “Prescriber” or “practitioner” means a licensed health care professional with authority to prescribe a controlled substance.
- k. “Prescription Drug Outlet” or “Dispenser” means any resident or nonresident pharmacy registered with the Board.
- l. “Qualified personnel” means persons who are appropriately trained to collect and analyze data for the purpose of conducting bona fide research or education.
- m. “Valid photographic identification” means any of the following forms of identification which include an identifying photograph:

1. A valid driver's license, or identification issued by any United States state;
 2. An official passport issued by any nation; or
 3. A United States armed forces identification card issued to active duty, reserve, and retired personnel and the personnel's dependents.
- n. "Zero Report" means a report submitted through the Colorado PDMP data submission environment confirming that no prescription dispensing transactions that would be required to be reported to the PDMP were completed for that date.

23.00.30 Data Submission Timeline.

- a. Every prescription drug outlet must ensure that all controlled substance dispensing transactions are reported to the PDMP on a daily basis by no later than the outlet's next regular business day.
- b. Prescription drug outlets that did not complete any controlled substance dispensing transactions for a date where the prescription drug outlet was open for business are required to submit a Zero Report to the Colorado PDMP for that date by no later than the next regular business day.
- c. Within 14 days of receiving its Out of State Prescription Drug Outlet (OSP) registration, out-of-state prescription drug outlets must submit a written attestation to the Board using the Board's approved Attestation form to exempt the out-of-state prescription drug outlet from prescription data reporting and Zero Reporting requirements.
- d. Within 14 days of receiving its DEA license, In-state prescription drug outlets (PDO registration) must submit a written attestation to the Board using the Board's approved Attestation form to exempt the prescription drug outlet from prescription data and zero report requirements.
- e. Prescription drug outlets that fail to report controlled substance dispensing transaction data or Zero Reports to the Colorado PDMP twice within a 30-day period will be referred to the Board of Pharmacy for possible discipline.

23.00.40 Data Submission Format.

Prescription drug outlets shall submit to the PDMP the required data fields listed below:

- a. Version/Release Number (TH01)
- b. Transaction Control Number (TH02)
- c. Transaction Type (TH03)
- d. Creation Date (TH05)
- e. Creation Time (TH06)
- f. File Type (TH07)
- g. Segment Terminator Character (TH09)
- h. Unique Information Source ID (IS01)

- i. Information Source Entity Name (IS02)
- j. Pharmacy DEA Number (PHA03)
- k. Pharmacy Name (PHA04)
- l. Pharmacy Address (PHA05)
- m. Pharmacy City Address (PHA07)
- n. Pharmacy State Address (PHA08)
- o. Pharmacy ZIP Code Address (PHA09)
- p. Patient Last Name (PAT07)
- q. Patient First Name (PAT08)
- r. Patient Address (PAT12)
- s. Patient City Address (PAT14)
- t. Patient State Address (PAT15)
- u. Patient ZIP Code Address (PAT16)
- v. Patient Date of Birth (PAT18)
- w. Patient Gender Code (PAT19)
- x. Reporting Status (DSP01)
- y. Prescription Number (DSP02)
- z. Prescription Date Written (DSP03)
- aa. Refills Authorized (DSP04)
- bb. Prescription Date Filled (DSP05)
- cc. Prescription Refill Number (DSP06)
- dd. Product ID Qualifier (DSP07, or CDI02 if a Compound)
- ee. Product ID (DSP08, or CDI03 if a Compound)
- ff. Quantity Dispensed (DSP09 and CDI04 for each ingredient if a Compound)
- gg. Days Supply (DSP10)
- hh. Drug Dosage Units Code (DSP11 or CDI05 if a Compound)
- ii. Classification Code for Payment Type (DSP16)
- jj. Date Sold (DSP17)

- kk. Prescriber DEA Number (PRE02)
- ll. Prescriber Last Name (PRE05)
- mm. Prescriber First Name (PRE06)
- nn. Detail Segment Count (TP01)
- oo. Transaction Control Number (TT01)

23.00.50 Data Correction.

- a. Any errors identified by the PDMP or a prescriber shall be acknowledged and resubmitted by the prescription drug outlet within 10 business days of notification of the error.
- b. Prescription drug outlets that fail to correct errors identified by the PDMP within 10 business days may be referred to the Board for possible discipline.

23.00.60 Patient Notification

Prescription Drug Outlets shall disclose to patients receiving controlled substance prescriptions that their prescription information is being submitted to the PDMP, and that this prescription information may be queried by specific individuals for a limited number of purposes as authorized by statute.

23.00.65 Unsolicited Reporting. In conjunction with other Colorado Boards who regulate prescribing practitioners and applicable stakeholders, the Board shall develop criteria for indicators of potential misuse, abuse and diversion of controlled substances and, based on those criteria, provide unsolicited reports of dispensed controlled substance prescriptions to the responsible prescribing practitioners and dispensing pharmacies of controlled substance(s) dispensed to the patient for purposes of education and intervention to prevent and reduce occurrences of controlled substance misuse, abuse, and diversion.

23.00.70 Release of PDMP Information

- a. The individual who is the recipient of a controlled substance prescription(s) so long as the information released is specific to such individual. The procedure for individuals to obtain such information is as follows:
 - 1. The individual shall submit a written, signed request to the Board on the Board-provided form;
 - 2. The individual shall provide valid photographic identification prior to obtaining the PDMP information;
 - 3. An individual submitting a request on behalf of another individual who is the recipient of a controlled substance prescription(s) may only obtain PDMP information if the following documents are provided:
 - (A) The original document establishing medical durable power of attorney of the individual submitting the request as power of attorney for the individual who is the recipient of the controlled substance prescription(s), and

- (B) Valid photographic identification of the individual submitting the request.
 - (C) A written, signed request to the Board on the Board-provided form signed by the individual submitting the request.
- 4. An individual submitting a request for a deceased individual ("decedent") who was the recipient of a controlled substance prescription(s) may only obtain PDMP information if the following documents are provided:
 - (A) A state-issued Certificate of Death for the decedent.
 - (B) A Court Order appointing the individual submitting the request as the Personal Representative of the Estate of the decedent who is the recipient of the controlled substance prescription(s).
 - (C) Valid photographic identification of the individual submitting the request.
 - (D) A written, signed request to the Board on the Board-provided form signed by the individual submitting the request.
- b. A person authorized to access the PDMP may knowingly release PDMP information specific to an individual or to the individual's treating providers in accordance with HIPAA, Pub.L. 104-191, as amended, and any rules promulgated pursuant to HIPAA without violating Part 4 of Title 12, Article 280.

23.00.80 Research or Education Agreements

The Board may enter into a written agreement to provide data to qualified personnel of a public or private entity for the purpose of bona fide research or education, so long as such information does not identify a recipient, prescriber, or dispenser of a prescription drug. Any public or private entity wishing to enter into or extend such an agreement shall submit a written request to the Board detailing the information it is seeking and the public benefit of such research or education. The Board will act on such request in the normal course of business.

23.00.90 Exemptions

- a. The following individuals or entities are exempt from reporting controlled substance dispensing transactions to the Prescription Drug Monitoring Program:
 - 1. Hospitals licensed or certified pursuant to section 25-1.5-103, C.R.S.;
 - 2. A prescription drug outlet located within a hospital licensed or certified pursuant to section 25-1.5-103, C.R.S., that dispenses controlled substances only pursuant to chart orders or dispenses no more than a 24-hour supply of a controlled substance to an outpatient. Pharmacies that meet these criteria must submit an attestation to the Board to exempt the pharmacy from daily data submission or zero reporting requirements. However, dispensations of more than a 24-hour supply must be submitted to the PDMP by the end of the following day.
 - 3. Emergency medical services personnel certified pursuant to section 25-3.5-203, C.R.S.; and

- 4. A prescription drug outlet which has applied to the Board and received a waiver from the Board. Waivers will only be considered if the pharmacy has no electronic automation. Such requests must be submitted in writing to the Board and will be considered in the normal course of business.
- b. Controlled substance dispensing transactions that occur solely for Institutional Review Board (IRB) approved interventional research trials using investigational drug products that are regulated by the Federal Food and Drug Administration shall be exempt from the data submission requirements of the PDMP.
- c. A prescription drug outlet which has submitted a written attestation to the Board that the pharmacy will never dispense controlled substance prescriptions to Colorado patients using the Board's approved Attestation form. Prescription drug outlets with a written attestation on file are also required to attest that the prescription drug outlet will never dispense such prescriptions in its registration renewal for the prescription drug outlet to remain exempt from data submission requirements.

24.00.00 CONFIDENTIAL AGREEMENTS

24.00.10 No later than thirty days from the date a physical or mental illness or condition impacts a pharmacist's or pharmacy intern's ability to practice pharmacy with reasonable skill and safety, the pharmacist or pharmacy intern shall provide the Board, in writing, the following information:

- a. The diagnosis and a description of the illness or condition;
- b. The date that the illness or condition was first diagnosed;
- c. The name of the current treatment provider and documentation from the current treatment provider confirming the diagnosis, date of onset, and treatment plan;
- d. A description of the pharmacist's or pharmacy intern's practice and any modifications, limitations or restrictions to that practice that have been made as a result of the illness or condition; and
- e. Whether the pharmacist or pharmacy intern has been evaluated by, or is currently receiving services from the Board's authorized Peer Health Assistance Diversion Program related to the illness or condition and, if so, the date of initial contact and whether services are ongoing.

24.00.20 The pharmacist or pharmacy intern shall further notify the Board of any significant change in the illness or condition ("change of condition") that impacts the pharmacist's or pharmacy intern's ability to practice pharmacy with reasonable skill and safety. The pharmacist or pharmacy intern must notify the Board of a positive or negative change of condition. Such notification shall occur within thirty days of the change of condition. The pharmacist or pharmacy intern shall provide the Board, in writing, the following information:

- a. The date of the change of condition;
- b. The name of the current treatment provider and documentation from the current treatment provider confirming the change of condition, the date that the condition changed, the nature of the change of condition, and the current treatment plan; and
- c. A description of the licensee's practice and any modifications, limitations or restrictions to that practice that have been made as a result of the change of condition.

- 24.00.30 Compliance with this Rule is a prerequisite for eligibility to enter into a Confidential Agreement with the Board pursuant to sections 12-280-136 and 12-30-108, C.R.S. However, mere compliance with this Rule does not require the Board to enter into a Confidential Agreement. Rather, the Board will evaluate all facts and circumstances to determine if a Confidential Agreement is appropriate.
- 24.00.40 If the Board discovers that a pharmacist or pharmacy intern has a mental or physical illness or condition that impacts the pharmacist's or pharmacy intern's ability to practice pharmacy with reasonable skill and safety and the pharmacist or pharmacy intern has not timely notified the Board of such illness or condition, the pharmacist or pharmacy intern shall not be eligible for a Confidential Agreement and may be subject to disciplinary action pursuant to section 12-280-126(1)(r), C.R.S.
- 24.00.50 A pharmacist or pharmacy intern who has a substance use disorder or engages in the habitual or excessive use or abuse of alcohol, a habit-forming drug, or a controlled substance as defined in section 12-280-126(1)(e), C.R.S., shall seek assistance from the Diversion Program as governed by section 12-280-204, C.R.S. Such pharmacists or pharmacy interns are not eligible to enter into a confidential agreement with the Board pursuant to sections 12-280-136 and 12-30-108, C.R.S.

25.00.00 SPECIALIZED PRESCRIPTION DRUG OUTLETS.

25.00.10 Definitions.

- a. "Automated device" or "AD" means a mechanical system that performs operations or activities relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains appropriate transaction information.
- b. "Hospice inpatient unit" means a facility as defined in section 15.5-4-103(8), C.R.S., that is licensed pursuant to section 25-1.5-103, C.R.S.
- c. "Long term care facility" or "LTCF" means a nursing facility as defined in section 25.5-4-103(14), C.R.S., that is licensed pursuant to section 25-1.5-103, C.R.S. An LTCF is a nursing home, skilled nursing facility or a nursing care facility that provides supportive, therapeutic, or compensating services with the availability of a licensed nurse for observation and treatment on a twenty-four hour basis.
- d. "Managing prescription drug outlet" means the prescription drug outlet located within the State of Colorado which is responsible for ownership and operation of a specialized prescription drug outlet located at an LTCF or hospice inpatient unit within Colorado. The managing prescription drug outlet is responsible for the application for the specialized prescription drug outlet on behalf of the LTCF or hospice inpatient unit. The managing prescription drug outlet shall own and operate the SPDO and maintain ownership of the drugs.
- e. "Specialized prescription drug outlet" or "SPDO" means an outlet located at an LTCF or hospice inpatient unit which is owned and operated by a managing prescription drug outlet located within the State of Colorado. The managing prescription drug outlet engages in the compounding, dispensing, and delivery of drugs and devices, or the provision of pharmaceutical care, residents of the LTCF or hospice inpatient unit. The managing prescription drug outlet may use automated devices in the SPDO to provide drugs, as well as other Board-approved nontraditional methods, to provide pharmaceutical care to the residents of the LTCF or hospice inpatient unit.

- f. "Stock drugs" mean non-patient specific prescription drugs or controlled substances that are distributed from a managing prescription drug outlet to a SPDO by means other than a patient-specific prescription order or LTCF or hospice inpatient unit chart order.
- 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 or hospice inpatient unit;
 - 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. 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
 - 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.
 - 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 section 12-280-103(8), C.R.S., only to the extent of distributing drug stocks to an SPDO.

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- 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. A complete and exact inventory of all stocks of controlled substances shall be conducted at each SPDO at least once every 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.

25.00.18 Policy and Procedure Manual.

- a. Each managing prescription drug outlet and corresponding SPDO shall maintain a policy and procedure manual which is approved by the Board or its designee prior to SPDO operation. This policy and procedure manual shall be reviewed, signed, and dated by both the pharmacist manager of the managing prescription drug outlet and the nursing home or hospice inpatient unit administrator or other accountable individual of the SPDO at least once annually. The pharmacist manager shall be responsible for assuring that the nursing home or hospice inpatient unit administrator or other accountable individual of the SPDO signs the policy and procedure manual.
- b. If a change in the pharmacist manager, or nursing home or hospice inpatient unit administrator or other accountable individual at the SPDO occurs, the new pharmacist manager and/or nursing home or hospice inpatient unit administrator or other accountable individual shall review, sign, and date the policy and procedure manual within thirty days of assuming the respective positions. The pharmacist manager shall be responsible for assuring that the new nursing home administrator or other accountable individual of the SPDO signs the policy and procedure manual.
- c. The policy and procedure manual shall, at minimum, address the accessibility to, the stocking of, the accountability and recordkeeping of, and the security of, the AD.

25.00.21 Relocation.

- a. In the event of a relocation of a SPDO, the managing prescription drug outlet shall submit an application form provided by the Division of Professions and Occupations along with the prescribed fee at least 30 days prior to the effective date of relocation.

25.00.22 Reinstatement of a SPDO Registration. If a registration of a SPDO has expired, the managing prescription drug outlet seeking to reinstate such SPDO registration shall submit an application on a form provided by the Division of Professions and Occupations along with the required fee.

25.00.24 Closure.

- a. Upon the closure of the SPDO it shall be the responsibility of the managing prescription drug outlet's pharmacist manager to remove all drug stocks from the LTCF or hospice inpatient unit within seventy-two hours after closure.
- b. The pharmacist manager of the managing prescription drug outlet shall notify the Board of the closure of the SPDO location within seven business days of the closure.

26.00.00 REMOTE PHARMACY PRACTICE.

26.00.10 Definitions

- a. "Drug regimen review" includes but is not limited to the evaluation of order(s) and patient records(s) for:
 - 1. Known allergies;
 - 2. Rational therapy and contraindications;
 - 3. Reasonable dose, duration of use, and route of administration considering age, gender, and other patient factors;
 - 4. Reasonable directions for use;
 - 5. Potential or actual adverse drug reactions;
 - 6. Drug-drug interactions;
 - 7. Drug-food interactions;
 - 8. Drug-disease contraindications;
 - 9. Therapeutic duplication;
 - 10. Proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and
 - 11. Abuse/misuse.
- b. "Final Evaluation" means the review of the final prescription to ensure that the ordered medication is properly prepared and placed in a suitable container with appropriate labeling. The pharmacist(s) conducting the final evaluation shall be held accountable for assuring that the identity of the drug that appears on the prescription label corresponds with identity of drug contained therein. When refills are dispensed, the pharmacist conducting the final evaluation shall be held accountable for the appropriate dispensing of refills including all drug utilization reviews as they pertain to refill dispensing.
- c. "Initial Interpretation" means the review of an order accompanied by order entry. The pharmacist(s) conducting the initial interpretation shall be held accountable for the accuracy of the electronic order entry/manual transcription and/or drug regimen review.
- d. "Remote Pharmacy Practice" may include, but is not limited to, duties conducted by pharmacists, pharmacy interns or pharmacy technicians at a location other than a registered prescription drug outlet or other outlet registered with the Board.
 - 1. Receiving and initially inputting new written, facsimile, or electronic orders;
 - 2. Maintaining proper records for drugs and devices;
 - 3. Transferring prescriptions;

4. Administrative duties that may include, but are not limited to: answering questions telephonically concerning pharmacy hours and operation, processing insurance claims, routing medication questions to the appropriate pharmacist on duty; and
5. Other activities as authorized and defined by the Board by rule.

26.00.20. Requirements for Remote Pharmacy Practice.

- a. A registered prescription drug outlet or other outlet may employ or contract with one or more pharmacists, pharmacy interns or pharmacy technicians for the purpose of conducting Remote Pharmacy Practice provided that all requirements, including those of confidentiality, privacy, and security are met, as required in this Rule.
- b. All pharmacists, pharmacy interns or pharmacy technicians employed or contracted with to conduct Remote Pharmacy Practice must hold an active, unrestricted license or certification with the Colorado State Board of Pharmacy;
- c. No drug inventory shall be stocked or maintained at any Remote Pharmacy Practice location;
- d. Pharmacists, pharmacy interns or pharmacy technicians engaged in Remote Pharmacy Practice are not considered in the computation of the technician to pharmacist ratio;
- e. All records of Remote Pharmacy Practice must be maintained at the prescription drug outlet or other outlet in accordance with applicable recordkeeping rules;
- f. Remote Pharmacy Practice shall have adequate security and be conducted in a setting sufficient to maintain patient privacy and confidentiality;
- g. Each prescription drug outlet or other outlet which employs or contracts with pharmacists, pharmacy interns or pharmacy technicians engaged in Remote Pharmacy Practice must maintain a written Policy and Procedure Manual. Such Policy and Procedure Manual shall be reviewed, updated, and revised as necessary to remain current, but at least annually. Written documentation of such review shall be maintained at the prescription drug outlet or other outlet. This policy and procedure manual shall be available for inspection upon request of the Board or its inspectors. This Policy and Procedure Manual shall include the following:
 1. Operation of the Remote Pharmacy Practice;
 2. Maintenance of security for Remote Pharmacy Practice;
 3. Procedure to ensure that Remote Pharmacy Practice shall be conducted in a manner in which patient privacy and confidentiality is maintained, including a provision that patient information may not be printed; and
 4. A detailed list of all pharmacists, pharmacy interns or pharmacy technicians engaged in Remote Pharmacy Practice and contact information for each pharmacist.

- h. The prescription drug outlet or other outlet shall enter into Written Agreements with each pharmacist, pharmacy interns or pharmacy technicians engaged in Remote Pharmacy Practice, detailing all conditions, and policies and procedures governing Remote Pharmacy Practice. Such agreement shall be reviewed, updated and revised no less than annually. Such agreement shall be maintained at the prescription drug outlet or other outlet and be available for inspection upon request of the Board or its inspectors; and
 - i. A pharmacist, pharmacy interns or pharmacy technicians conducting Remote Pharmacy Practice is responsible for ensuring that his or her Remote Pharmacy Practice is conducted in accordance with the Policy and Procedure Manual and Written Agreement.
- 26.00.40. Equipment. All equipment, including computer equipment, utilized for Remote Pharmacy Practice shall meet at least the following requirements:
 - a. Computer equipment must be able to establish a secure internet connection;
 - b. Equipment must be configured so patient information may not be stored at the site at which Remote Pharmacy Practice is occurring;
 - c. Access to the site for Remote Pharmacy Practice must be locked or shut down when the pharmacist ceases to be engaged in Remote Pharmacy Practice; and
 - d. Security parameters must prevent unauthorized storage or transfer of patient information.
- 26.00.50 Requirements for Conducting Final Evaluation. If Remote Pharmacy Practice includes conducting the final evaluation of prescriptions for a prescription drug outlet or other outlet, the following requirements apply:
 - a. The pharmacist must have a visual connection with the prescription drug outlet or other outlet for the pharmacist to review the finished product prior to delivery to the patient; and
 - b. The prescription drug outlet or other outlet shall maintain records of final evaluation in accordance with all other applicable recordkeeping requirements.
- 27.00.00 HOSPITAL SATELLITE PHARMACY.**
- 27.00.10 Definitions.
 - a. "Hospital satellite pharmacy (HSP)" is a pharmacy located in a facility under the same management or control as the building or site where the hospital's Primary pharmacy is located, has a different address than the primary pharmacy, and is housed in a building with a main entrance that is no more than one mile from the main entrance to the building which houses the primary pharmacy. Hospital satellite pharmacies may stock drugs at areas of the building where the hospital pharmacy is located, provided the areas are under the same management or control as the building or site where the hospital's primary pharmacy is located. The one mile requirement shall not apply if a public health order is in effect and consequently requires a greater distance temporarily.
 - b. "Primary pharmacy" is a registered prescription drug outlet in the hospital where the principal compounding/dispensing area is located.
- 27.00.20 Registration requirements.
 - a. Hospitals which own or operate a pharmacy shall register all HSPs.

- b. The primary pharmacy shall submit an application on a form provided by the Division of Professions and Occupations on behalf of the HSP and for any drug storage satellites at the same location as the HSP.
- c. HSPs and any drug storage satellites placed at the same location as the HSP must pass a pre-registration inspection by the Board or its inspectors prior to registration.
- d. Any existing HSP or drug storage satellite at the same location as the HSP which is being remodeled or is being moved from one area of the location of the HSP to another shall submit documentation required by the Board prior to remodeling or moving.
- e. The compounding/dispensing area of an HSP shall not be less than 100 continuous square feet and must be approved by the Board prior to use for the practice of pharmacy.
- f. Any room included within or adjacent to the compounding/dispensing area that is separated from the compounding/dispensing area by a door must meet the following:
 - 1. The HSP shall submit documentation required by the Board to remodel the compounding/dispensing area prior to the utilizing the room 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 compounding/dispensing area, that states "This room is part of the approved designated compounding/dispensing area";
 - 3. Unless the door is used to secure a room dedicated to storing controlled substances, it shall not have the ability to be locked or otherwise secured. The Board or its representatives shall have readily available and unimpeded access to this room at all times during normal business hours; and
 - 4. If a locked or otherwise secured door is used to secure a room dedicated to storing controlled substances, it shall be unlocked immediately upon the request of the Board or its representatives.
- g. Up to two satellites at the same location as the HSP 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.
- h. All HSPs and all 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.
- i. If the HSP engages in compounding/dispensing, there shall be a minimum of twelve continuous square feet of compounding/dispensing area, and a minimum of six continuous square feet of compounding/dispensing area for each person engaged in compounding/dispensing. 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.

- j. The free floor space behind any compounding/dispensing counters or work surfaces shall be not less than thirty inches in width;
- k. The free floor space between rows of shelving shall be not less than twenty-four inches;
- l. If the HSP engages in compounding/dispensing, there shall be sufficient shelf, drawer and/or cabinet space for proper storage of prescription drugs and devices.
- m. If the HSP engages in compounding/dispensing, 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.
- n. Any other professional and technical equipment appropriate and adequate for the type of practices the HSP engages in shall at all times be located within the compounding/dispensing area.
- o. If refrigerated drugs are stored at the HSP or drug storage 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 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 HSP 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.
- p. If frozen drugs are stored at the HSP or drug storage 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 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 HSP 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.
- q. There shall be a professional reference library available in the HSP. If an electronic library is provided, workstations must be provided in the 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. Title 12, Article 280, C.R.S.; the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.
 - 2. CRS Title 18, Article 18, the Uniform Controlled Substances Act of 1992;
 - 3. Board of Pharmacy 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, the 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 primary pharmacy may deem necessary.
- r. The preceding subsections under 27.00.20(c),(e),(f),(i),(m), and (q) shall not apply if a public health order is in effect and consequently and temporarily impacts timely compliance with such requirements. The Pharmacy and staff will make attempts to the best of their ability to ensure compliance is achieved in as timely a manner as possible, and document such efforts.

27.00.30 Requirements for operation of an HSP

- a. The pharmacist manager of the primary pharmacy shall have responsibility for the operation and control of the HSP;
- b. For the purpose of recordkeeping, drug stocks of the HSP shall be included in the inventory of the primary pharmacy;
- c. All records from the HSP shall be maintained at the primary pharmacy in accordance with Rule 11.00.00;
- d. Pharmacist staffing at the HSP cannot be considered in the computation of the pharmacists to pharmacy technician ratio in the primary pharmacy;
- e. Pharmacist staffing at the primary pharmacy cannot be considered in the computation of the pharmacists to pharmacy technician ratio in the HSP;
- f. The primary pharmacy may distribute drugs to the HSP in the same manner it would to other units of the hospital, and records shall be maintained in accordance with Rule 11.07.10;
- g. Every HSP shall display in the HSP 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
- h. No person other than a pharmacist or intern employed by the HSP shall be permitted in the compounding/dispensing area without the consent of the pharmacist in charge of the compounding/dispensing area.

27.00.40 Minimum Hours of Operation

- a. The principal compounding/dispensing area of an HSP 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. This requirement shall not apply if a public health order is in effect and consequently and temporarily impacts operating hours.
- b. In the event that the principal compounding/dispensing area is open less than thirty-two 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 thirty days prior to the date on which the hours of operation will be less than thirty-two hours per week.

27.00.50 Security. All HSPs and additional satellites shall comply with this Rule.

- a. When any compounding/dispensing area of an HSP is occupied by any employee, a pharmacist must be physically present within the same building of the HSP.
- 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.
- d. If more than one HSP 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.
- e. An HSP 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 where the HSP is located. 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 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;

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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 building where the HSP is located is open, a person on duty in the building shall be able to contact a pharmacist in case of emergency.
 - h. No HSP 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.
 - i. Procedures to follow in an emergency situation when a pharmacist is not in the building where the HSP is located are as follows:
 1. In an emergency situation and when a pharmacist is not in the building where the HSP is and administration of a drug to, or use of a device by or on, a 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 containers, 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 two 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 returns to the building. Additional quantities of the drug or device shall be supplied by a pharmacist and properly recorded as required by law and rule.
- 27.00.70 Relocation. In the event of a relocation of an HSP, the primary pharmacy shall submit an application on a form provided by the Division of Professions and Occupations along with the required fee at least thirty days prior to the effective date of relocation.
- 27.00.80 Reinstatement of an HSP registration. If a registration of an HSP has expired, the primary pharmacy shall submit a reinstatement application on a form provided by the Division of Professions and Occupations along with the required fee.
- 27.00.90 Closure.
- a. Closure shall mean the permanent cessation of the practice of pharmacy in any HSP. Closure shall also be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in Rule 27.00.40.
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- b. Upon the closure of the HSP, it shall be the responsibility of the pharmacist manager of the primary pharmacy to relocate the chart orders and drugs to the primary pharmacy. Such relocation of records shall be made within seventy-two hours after closure of the HSP. The pharmacist manager shall notify the Board on a form provided by the Board, detailing the closure of the HSP within seventy-two hours after closure. If the pharmacist manager fails to relocate the drugs and records as required herein, the Board may direct the removal of the drugs and records to a suitable location.

28.00.00 VETERINARY PHARMACEUTICAL ADVISORY COMMITTEE.

28.00.10 Definitions.

- a. "Board" means the Colorado State Board of Pharmacy.
- b. "Veterinary Pharmaceutical" means a prescription drug that is any of the following:
 - (1) Intended solely for animal use;
 - (2) Distributed for animal use;
 - (3) Dispensed for animal use;
 - (4) Administered to an animal.
- c. "Veterinary Pharmaceutical Advisory Committee (Advisory Committee)" is a committee comprised of three members, each appointed by the state veterinarian, which reviews matters concerning veterinary pharmaceuticals, as specified by this Rule 28.00.00, referred to it by the Board and which makes recommendations on how the Board should proceed on the matters.

28.00.20 Matters Referred by the Board to the Advisory Committee Specified. Unless a matter presented to the Board constitutes an emergency requiring prompt resolution, the Board shall refer the following matters that directly concern veterinary pharmaceuticals to the Advisory Committee for recommendation on how the Board should proceed on the matter:

- a. Whether and to what extent action, if any, should be taken on an investigation into or complaint of an alleged violation of Article 280 of Title 12, C.R.S., as it directly pertains to the distribution, dispensation or administration of a veterinary pharmaceutical to an animal, including whether to:
 - (1) Suspend or revoke a license or registration;
 - (2) Impose a fine against a registrant, whether the violation is egregious, and the amount of any fine recommended;
 - (3) Seek a cease and desist order or injunction in district court against an entity or person; or
 - (4) Pursue other disciplinary action against a licensee or registrant.
- b. Review of license and registration applications and renewal, reactivation, and reinstatement applications when there is evidence the applicant directly engages in the distribution, dispensation, or administration of veterinary pharmaceuticals solely to animals; and,

- c. Promulgation of rules as they pertain to the distribution, dispensation, or administration of veterinary pharmaceuticals solely to animals.

29.00.00 PHARMACY TECHNICIANS

Rule 29.00.30 Certification requirements.

- a. An applicant for a provisional or non-provisional certification shall submit an application as provided by the Board and the prescribed fee.
- b. An applicant for a non-provisional certification shall submit proof that the applicant is certified by a nationally recognized certification board or body. For the purpose of obtaining a Board-issued non-provisional certification to practice as a pharmacy technician, the Board defines a “nationally recognized certification board or body” for pharmacy technicians as those boards or bodies approved by the National Association of Boards of Pharmacy (NABP) or the National Commission of Certifying Agencies (NCCA).
- c. Each applicant for a provisional or non-provisional certification shall provide proof satisfactory to the Board that the applicant submitted to a criminal history check as a condition of employment at a pharmacy or other outlet, as required by the applicant’s current employer, as a condition of participating in a course of study for or with a certifying board or body, or in connection with obtaining certification from a certifying board or body.

29.00.50 Process for provisional certificant to apply for a hardship extension to extend the validity of a provisional certification beyond eighteen (18) months. The Board will consider criteria for qualifying for a one-time, fee-waived, nine (9) month hardship extension of a provisional certification based on the receipt of a detailed written explanation submitted to the Board at least sixty (60) days prior to the expiration date of the provisional certification based on:

- a. The negative effects on access to care in the community served by the provisional certificant or the employer of the provisional certificant;
- b. Financial hardship; or
- c. Health circumstances.

31.00.00 Telepharmacies.

31.00.05 Definitions.

- a. “Area of need” means any health facility licensed or certified by the Department of Public Health and Environment pursuant to section 25-1.5-103(1), C.R.S., or any area where a demonstration of need is approved by the Board.
- b. “Central pharmacy” means a registered prescription drug outlet located in Colorado which is responsible for overseeing the operation of no more than two (2) telepharmacies.
- c. “Telepharmacy” has the same meaning as set forth in section 12-280-103(50), C.R.S.

31.00.10. Application Requirements.

- 31.00.11 Registration. The applicant for registration shall obtain the appropriate form as approved by the Board to register a telepharmacy. In the case of an application for a new telepharmacy, for a transfer of ownership of a telepharmacy, or for the relocation of a telepharmacy, the applicant shall submit such additional documentation as the Board may require.
- 31.00.15 Applications. The Board, or its agent, may require any applicant or pharmacist manager of a telepharmacy to meet with the Board, or its agent, before the Board takes action on any registration.
- 31.00.20 No two registered outlets may occupy the same physical space. If there are two (or more) registrants co-located within the same building or at the same address, each must have its own area, separated by floor to ceiling walls, and separate entrances.
- 31.00.30 Transfer of Ownership. Application to transfer registration of a telepharmacy shall be submitted to the Board as provided in section 12-280-118, C.R.S., within thirty (30) days of the transfer of ownership. A transfer of ownership shall be deemed to have occurred:
- a. In the event the telepharmacy is owned by a corporation, upon sale or transfer of twenty percent or more of the shares of said corporation to a single individual or entity.
 - b. In the event the telepharmacy is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.
 - c. In the event the telepharmacy is owned by a limited liability company (LLC), upon sale or transfer of twenty percent or more of the membership interests.
 - d. Upon incorporation of an existing telepharmacy.
- 31.00.40 Relocation. In the event of a relocation of a telepharmacy shall submit an application provided by the board along with the prescribed fee no more than thirty (30) days prior to the effective date of relocation.
- 31.00.50 Reinstatement of a Telepharmacy Registration.
- a. If a registration has expired, a telepharmacy seeking to reinstate such registration shall submit the following:
 - (1) The current reinstatement application with the required fee;
 - (2) If the owner of the telepharmacy is a corporation, submit either a copy of the articles of incorporation as they were filed with the Colorado Secretary of State or a Certificate of Good Standing issued by the Colorado Secretary of State;
 - (3) A letter stating whether the corporation is public or private as follows:
 - (A) If the corporation is a public corporation, submit a list of all stockholders owning five percent or more of the stock; or
 - (B) If the corporation is a private corporation, submit a list of all stockholders;
 - (4) An accurate drawn-to-scale floor plan of the telepharmacy's compounding / dispensing area detailing all counters, bays, sinks, refrigerators and, if applicable, sterile and non-sterile compounding hoods; and

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

31.00.60 Closure.

- a. Closure shall mean the permanent cessation of the practice of pharmacy in any telepharmacy.
- b. Upon the closure of any telepharmacy, it shall be the responsibility of the last pharmacist manager of record to remove the orders, if applicable, to another telepharmacy or 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 seventy-two hours after closure. The pharmacist manager shall submit a notice, on a form and manner approved by the Board, detailing the closure of the telepharmacy within seventy-two hours after closure. 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 telepharmacy of the location of the records.
- c. The Board on request shall provide the owner of any telepharmacy an instruction sheet applicable to the transaction prior to closure, or conducting bankruptcy proceedings, or transferring or selling the prescription drug inventory.

31.01.00 Structural Requirements.

31.01.10 Within every telepharmacy there shall be one area designated as the principal compounding/dispensing area. The principal compounding/dispensing area shall comply with the following conditions:

- a. The principal compounding/dispensing area shall not be less than 150 continuous square feet.
- b. 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 telepharmacy 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.
- c. All compounding/dispensing areas 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.

- d. In every telepharmacy where compounding or dispensing is physically occurring, there shall be a minimum of twelve continuous square feet of free and clear counter space, and a minimum of six continuous square feet of free and clear counter space for each person engaged in compounding/dispensing. 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 thirty inches in width;
 - (2) The free floor space between shelving rows shall be not less than twenty-four inches; and
 - (3) There shall be sufficient shelf, drawer and/or cabinet space for proper storage of prescription drugs and devices.
- e. 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.
- f. The telepharmacy shall have all the technical equipment necessary for the appropriate compounding and dispensing it conducts and as required pursuant to section 12-280-103(50), C.R.S.
- g. If refrigerated drugs are stored in the principal compounding/dispensing area, 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.) or in accordance with the corresponding drug manufacturer's directions. 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.
- h. If frozen drugs are stored in the principal compounding/dispensing area, 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.) or in accordance with the corresponding drug manufacturer's directions. 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.

- i. Every telepharmacy 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 telepharmacy.
- 31.02.00 Staffing and Training Requirements. Only a Colorado licensed pharmacist, Colorado-licensed pharmacy intern, or Colorado-certified pharmacy technician may engage in the practice of pharmacy. All personnel engaged in the practice of pharmacy shall be adequately trained to, as applicable to the practice setting, dispense and compound prescriptions and administer vaccines.
- 31.03.00 Pharmacist Manager or Licensed Pharmacist Delegate Visitation Requirements. The pharmacist manager or licensed pharmacist delegate shall visit the telepharmacy at least once monthly. Documentation of these visits shall be readily available and retrievable for inspection at the telepharmacy upon the request of the Board or its representatives for at least two years preceding the request.
- 31.04.00 Security in every telepharmacy, 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 or Board-certified pharmacy technician must be physically present within the same building of the telepharmacy. This Rule shall not apply if the telepharmacy does not possess prescription drug or controlled substance stocks or patient information within the first 120 calendar days after the telepharmacy has been registered by the Board.
 - b. In the event a pharmacist or Board-certified pharmacy technician is within the building but absent from a compounding/dispensing area, it is the responsibility of the pharmacist or Board-certified pharmacy technician to ensure the proper safeguard of all drugs.
 - c. If a compounding/dispensing area is continually attended by a pharmacist or Board-certified pharmacy technician 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 or Board-certified pharmacy technician 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 Rule 31.04.00(a).
 - d. If more than one telepharmacy is located within the same building, a pharmacist or Board-certified pharmacy technician shall not operate more than one telepharmacy at the same time. If a pharmacist or Board-certified pharmacy technician 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 or Board-certified pharmacy technician shall be enclosed by a barrier as specified in paragraph e below and a non-pharmacist or non-Board-certified pharmacy technician shall not remain inside the enclosed outlet during that time unless the telepharmacy qualifies for the exemption provided under Rule 5.01.50(a).

- e. A telepharmacy 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 or Board-certified pharmacy technician leaves the building except as provided in Rule 5.01.50(a). No one other than a Board-certified pharmacy technician 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 Board-certified pharmacy technician or left unsecured from unauthorized entry when the pharmacist or Board-certified pharmacy technician 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.

31.05.00 Unless as otherwise specified in this Board Rule 31.00.00, telepharmacies shall, as applicable, operate and maintain such records as required by the Board for prescription drug outlets relating to, but not limited to, the receipt, storage, dispensing, administration, prepackaging, compounding and other disposition of prescription drugs and controlled substances.

31.06.00 The pharmacist manager shall be responsible for the operations of a telepharmacy in compliance with all applicable state and federal rules and laws pertaining to drugs.

32.00.00 CONCERNING HEALTH CARE PROVIDER DISCLOSURES TO CONSUMERS ABOUT THE POTENTIAL EFFECTS OF RECEIVING EMERGENCY OR NONEMERGENCY SERVICES FROM AN OUT-OF-NETWORK PROVIDER

- A. Basis: The basis for this rule is to implement the requirements of section 12-30-112, C.R.S., in consultation with the Commissioner of Insurance and the State Board of Health.
- B. Purpose: The purpose of these rules and regulations is to establish the requirements for healthcare providers to provide disclosures to consumers about the potential effects of receiving emergency or non-emergency services from an out-of-network provider as required by section 12-30-112, C.R.S.
- C. Definitions, for purposes of this Rule, are as follows:

1. "Publicly available" means, for the purposes of this regulation, searchable on the healthcare provider's public website, displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. The health care provider's public website must be accessible free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information.
- D. Disclosure requirements.
1. An out of network provider may balance bill a covered person for post-stabilization services in accordance with section 10-16-704, C.R.S., and covered nonemergency services in an in-network facility that are not ancillary services if the provider meets the requirements set forth in section 12-30-112(3.5), C.R.S. If a consumer has incurred a claim for emergency or nonemergency health care services from an out-of-network provider, the health care provider shall provide the disclosures contained in Appendix F in compliance with section 12-30-112(3.5), C.R.S.
 2. The health care provider shall provide the disclosure contained in Appendix F as set forth in section 12-30-112(3.5), C.R.S.:
- E. **Noncompliance with this Rule may result in the imposition of any of discipline made available by section 12-280-126(1)(c), C.R.S. Appendix A**

33.00.00 RULES AND REGULATIONS REGARDING GENERALLY ACCEPTED STANDARDS OF PHARMACY PRACTICE REGARDING PREGNANCY-RELATED SERVICES

- A. Basis: The authority for promulgation of Rule 33.00.00 ("these Rules") by the Colorado Board of Pharmacy ("Board") is set forth in sections 24-4-103, 12-280-107, and 12-30-120(2), C.R.S.
- B. Purpose: The purpose of these rules and regulations is to implement the requirements of section 12-30-120(2), C.R.S.
- C. Definitions
1. "Abortion" has the meaning set forth in section 25-6-402(1), C.R.S.
 2. "Medication abortion" has the meaning set forth in section 12-30-120(1)(b), C.R.S.
 3. "Medication abortion reversal" has the meaning set forth in section 12-30-120(1)(c), C.R.S.
- D. Standard of Care Considerations
1. Compliance with generally accepted standards of pharmacy practice requires a licensee to exercise the same degree of knowledge, skill, and care as exercised by licensees in the same field of practice at the time care is rendered.
 2. The Board evaluates generally accepted standards of pharmacy practice on a case-by-case basis. Each instance of pharmacy care will involve its own unique set of facts that the Board must evaluate against the backdrop of evidence-based practice standards. For that reason, the Board does not regularly adopt rules establishing a single standard of care applicable to all situations.

3. The Board will not treat medication abortion reversal as a per se act of unprofessional conduct. Rather, the Board will investigate all complaints related to medication abortion reversal in the same manner that it investigates other alleged deviations from generally accepted standards of pharmacy practice under section 12-280-126(1)(k), C.R.S.

Appendix A

Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing Contraceptives

(Appendix A)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to perform the pertinent physical assessments and prescribe contraceptives under the conditions of this protocol and according to and in compliance with all applicable state and federal laws and rules.

Definitions

- (1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.
- (2) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.
- (3) "Oral hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.
- (4) "Vaginal ring" means a plastic ring, inserted vaginally by the patient that releases a combination or hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.
- (5) "DPMA" means Depot Medroxyprogesterone Acetate, an injection, administered every three months by a pharmacist of patient that is approved by the United States Food and Drug Administration to prevent pregnancy.

Training Program

Only a Colorado-licensed pharmacist, who has completed an Accreditation Council for Pharmacy Education (ACPE) accredited educational training program related to the prescribing of contraceptives by a pharmacist may, if clinically appropriate, prescribe, dispense, or administer hormonal contraceptives to a patient. In addition, pharmacists shall comply with the most current United States Medical Eligibility Criteria (USMEC) for Contraceptive Use as adopted by the U.S. Centers for Disease Control and Prevention (CDC).

Age Requirements

A pharmacist may prescribe hormonal contraceptives to a person who is at least 18 years of age.

Further Conditions

- (1) For each new patient requesting a contraceptive service and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:
 - (a) Obtain a completed patient self-screening risk- assessment questionnaire;
 - (b) Assess what contraceptive options are appropriate for the patient through a consistent and standardized process;

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- (c) May prescribe, if clinically appropriate, the hormonal contraceptive patch, self-administered oral hormonal contraceptive, DMPA, Vaginal Ring, or refer to a healthcare practitioner;
 - (d) Provide the patient with a visit summary;
 - (e) Advise the patient to consult with a primary care practitioner or women's health care practitioner;
 - (f) Refer any patient that may be subject to abuse to an appropriate social services agency; and
 - (g) Ensure that the pharmacy provides appropriate space to prevent the spread of infection and provide appropriate consultation and ensure confidentiality.
- (2) If the contraceptive is dispensed or administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.
- (3) A pharmacist must not:
- (a) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive;
 - (b) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit; or
 - (c) Prescribe in instances when referral to a primary care provider is more appropriate.
- (4) Records:
- (a) Pursuant to Pharmacy Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
 - (b) Pharmacists shall comply with all aspects of Pharmacy Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

Appendix B

Colorado State Board of Pharmacy Approved Statewide Protocol for Dispensing Tobacco Cessation Products

(Appendix B)

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to dispense safe and effective tobacco cessation products according to and in compliance with all applicable state and federal laws and rules.

The pharmacists will perform health screening according to this protocol and may then determine the need for and dispense a tobacco cessation product pursuant to the terms of the attached protocol.

Pharmacists must have a valid Colorado pharmacist license and have completed an Accreditation Council for Pharmacy Education (ACPE) accredited program in tobacco cessation.

The pharmacy shall ensure that appropriate space is provided to prevent the spread of infection and to ensure confidentiality.

Protocol

PHARMACISTS GENERAL REQUIREMENTS:

- a. All pharmacists participating in this protocol for tobacco cessation drug therapy will follow the US Department of Health and Human Services, Public Health Services, Clinical Practice Guideline: Treating Tobacco Use and Dependence: 2008 Update (or subsequent updates as they become available). Additionally, all product information (PI) and dosing from any products dispensed;
- b. Pharmacists will implement the Five A's (ask, advise, assess, assist, arrange) to help patients quit using all forms of tobacco; and
- c. Pharmacists services will include an educational component to include counseling on medication therapies and cessation strategies as well as referral to sources provided by the Colorado Quit Line program.

SCREENING AND HISTORY

- a. Under this protocol, pharmacists should offer assistance to tobacco users motivated and ready to quit. Medications should be offered as appropriate.
- b. A standardized screening tool will be used to assess the following for each patient intending to use medications:
 - 1. Medical and social history including current medications;
 - 2. Previous medication attempts, failures, intolerances;
 - 3. Allergies and hypersensitivities;
 - 4. Potential drug interactions with potential medication treatments (per Guidelines/Dispensing Information);

5. Precautions/contraindications of potential medication treatments (per Guidelines/Dispensing Information); and
 6. Patient preferences with regards to treatment options
- c. A standardized screening tool will be used to identify patients who do NOT qualify for specified medication therapies under this protocol and will be referred to a primary care provider for further assessment:
1. Age under 18 years (any/all medications);
 2. Pregnancy or plan to become pregnant (any/all medications);
 3. History of seizure disorder (bupropion);
 4. History of eating disorder (bupropion);
 5. History of mental illness / psychiatric disorder (bupropion or varenicline);
 6. Patients undergoing abrupt discontinuation of alcohol, benzodiazepines, barbiturates, and antiepileptic drugs (bupropion);
 7. Hypersensitivity to any previous use of nicotine, bupropion or varenicline;
 8. Use of a monoamine oxidase inhibitor (MAOI) within 14 days (bupropion);
 9. Recent history of myocardial infarction (within 14 days), serious cardiac arrhythmias, unstable or severe angina (nicotine replacement);
 10. Known moderate/severe hepatic or renal impairment (any/all medications); and
 11. Smokeless tobacco use (any/all medications).

DISPENSING

- a. FDA First-Line Approved Medications which may be prescribed (dosing per Clinical Practice Guidelines/Package Inserts). This information should be updated no less frequently than every 2 years.

1. Nicotine Replacement Therapies

Patch

- Treatment of 8 weeks or less has been shown to be as efficacious as longer treatment periods. Patches of different doses sometimes are available as well as different recommended dosing regimens. Clinicians should consider individualizing treatment based on specific patient characteristics, such as previous experience with the patch, amount smoked, degree of dependence, etc.

- Step-down Dosage

| | |
|--------------|----------------|
| 4 weeks | 21 mg/24 hours |
| then 2 weeks | 14 mg/24 hours |
| then 2 weeks | 7 mg/24 hours |

Gum

- Nicotine gum is available in 2-mg and 4-mg (per piece) doses. The 2-mg gum is recommended for patients smoking less than 25 cigarettes per day; the 4-mg gum is recommended for patients smoking 25 or more cigarettes per day. Smokers should use at least one piece every 1 to 2 hours for the first 6 weeks; the gum should be used for up to 12 weeks with no more than 24 pieces to be used per day.

Lozenge

- Nicotine lozenges are available in 2-mg and 4-mg (per piece) doses. The 2-mg lozenge is recommended for patients who smoke their first cigarette more than 30 minutes after waking, and the 4-mg lozenge is recommended for patients who smoke their first cigarette within 30 minutes of waking. Generally, smokers should use at least nine lozenges per day in the first 6 weeks; the lozenge should be used for up to 12 weeks, with no more than 20 lozenges to be used per day.

Nasal Spray

- A dose of nicotine nasal spray consists of one 0.5-mg dose delivered to each nostril (1 mg total). Initial dosing should be 1–2 doses per hour, increasing as needed for symptom relief. Minimum recommended treatment is 8 doses/day, with a maximum limit of 40 doses/day (5 doses/hour). Each bottle contains approximately 100 doses. Recommended duration of therapy is 3–6 months.

Inhaler

- A dose from the nicotine inhaler consists of a puff or inhalation. Each cartridge delivers a total of 4 mg of nicotine over 80 inhalations. Recommended dosage is 6–16 cartridges/day. Recommended duration of therapy is up to 6 months. Patient should taper dosage during the final 3 months of treatment.

2. Bupropion

- Begin bupropion SR treatment 1–2 weeks before they quit smoking. Patients should begin with a dose of 150 mg every morning for 3 days, then increase to 150 mg twice daily. Dosage should not exceed 300 mg per day. Dosing at 150 mg twice daily should continue for 7–12 weeks. For long-term therapy, consider use of bupropion SR 150 mg for up to 6 months post-quit.

3. Varenicline

- Start varenicline 1 week before the quit date at 0.5 mg once daily, followed by 0.5 mg twice daily for 4 days, followed by 1 mg twice daily for 3 months. Varenicline is approved for a maintenance indication for up to 6 months. Note: Patient should be instructed to quit smoking on day 8 when dosage is increased to 1 mg twice daily.

4. Evidence-Based Combination Therapies
 - Bupropion + Nicotine patch (standard dosing as detailed above). If this combination is used, patient shall be monitored for treatment emergent hypertension and include a follow up blood pressure within 1-2 weeks.
 - Long term nicotine patch (>14 weeks) + other nicotine replacement products (gum and spray) – doses as detailed above.
 - Nicotine patch + Nicotine inhaler (doses as detailed above)
- b. Duration of the above therapies, if not specifically detailed above, shall not exceed 6 months.
- c. Dosing, Precautions, Contraindications and Monitoring considerations shall follow Clinical Practice Guidelines and manufacturer prescribing information.
- d. Patients will be supplied with written educational information on any therapies prescribed.
- e. Pharmacists will implement an appropriate monitoring and follow up plan with each patient.
- f. Pharmacists may continue to provide over-the-counter smoking cessation products to tobacco users without the use of this protocol.

RECORDS

- a. Pursuant to Pharmacy Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.
- b. Pharmacists shall comply with all aspects of Pharmacy Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

Appendix C

Colorado State Board of Pharmacy Statewide Protocol

Pre-Exposure and Post-Exposure Prophylaxis of HIV

This collaborative pharmacy practice statewide protocol authorizes qualified Colorado-licensed pharmacists ("Pharmacists") to provide pertinent assessment of risk of HIV acquisition and prescribe pre-exposure and post-exposure prophylaxis medications for the prevention of HIV infection according to and in compliance with all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the U.S. Centers for Disease Control and Prevention (CDC)^{1, 3} and the United States Preventive Services Task Force (USPSTF)².

Prior to prescribing and dispensing HIV prevention medication per this protocol, the pharmacist must:

1. Hold a current license to practice in Colorado
2. Be engaged in the practice of pharmacy
3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist
4. Carry adequate professional liability insurance as determined by the Board
5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.)
6. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00.

The pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality. Records:

- A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and lab test(s) ordered, and any test results.
- B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

Pre-Exposure Prophylaxis (PrEP) Protocol

Under this protocol, Pharmacists may assess for HIV status and high-risk behaviors in which pre-exposure prophylaxis against HIV would be warranted.

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table Ia, or other

FDA approved/CDC recommended medications or regimens can be used if they become available, according to the following criteria:

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care antigen/antibody fingerstick blood test, or by drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test with results being received within 7 days prior to the initiation of PrEP. Neither oral swab testing nor patient report of negative status are acceptable for evidence.
2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:
 - a. Sexually-Active Adults
 - Without acute or established HIV infection
 - Anal or vaginal sex in the past 6 months
 - AND at least one of the following:
 - HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
 - Has tested positive for bacterial STI in the past 6 months
 - Gonorrhea, Chlamydia, and Syphilis for men who have sex with men (MSM) and transgender women (TGW) who have sex with men, including those who inject drugs
 - Gonorrhea and Syphilis for heterosexual women and men including persons who inject drugs
 - b. Persons Who Inject Drugs (PWID)
 - Adult person
 - Without acute or established HIV infection
 - Any injection of drugs not prescribed by a clinician in past 6 months
 - AND any of the following:
 - Any sharing of injection or drug preparation equipment in past 6 months
 - Risk` of sexual acquisition (see above)
 - c. Any patient who requests PrEP, even if no specific risk behaviors are elicited

Patients who should NOT be prescribed PrEP under this protocol and should be referred to primary care provider for further action:

- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest acute HIV infection not yet detectable (fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, diarrhea)
- Patients on medications contraindicated with PrEP therapy selected
- Patients with history of hypersensitivity reaction to PrEP therapy selected

TABLE 1a – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available.

Formulations, cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Frequency | Duration of Therapy | Notes |
|---|------------|------------|---|--|
| FTC/TDF (F/TAF) emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) | ≥35 kg | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CRCL <60 ml/min. |
| FTC/TAF (F/TAF) emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®) | ≥35 kg | Once daily | Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up. | May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert. |

| | | | | |
|---|-----------------|---|--|--|
| CAB Cabotegravir 600mg/3mL (Apretude®) extended-release injectable suspension for intramuscular (IM) use | <p>>35kg</p> | <p>Month 1: 4-week optional oral lead in of daily cabotegravir 30mg (Vocabria®) tablet Month 2: 600mg (3mL) IM gluteal injection administered by healthcare professional on last day of oral therapy or within 3 days of last oral dose Month 3 (and every 2 months thereafter): 600mg (3ml) IM gluteal Injection administered by healthcare professional</p> | <p>Prescription issued for 1 injection at a time following the dosing and lab schedule</p> | <p>See package insert for instructions regarding planned or unplanned missed injections Drug resistant HIV-1 variants have been identified with use of Apretude® (Black Box Warning)</p> |
|---|-----------------|---|--|--|

Labs:

- PrEP cannot be started without a negative HIV Ag/Ab test at baseline.
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab results.
- PrEP refills will not be authorized past the initial 30 day supply for oral therapy if recommended baseline testing is not done by one of the above mechanisms.
- PrEP refills will not be authorized in absence of scheduled follow up for injectable therapy

TABLE 2a – ROUTINE REQUIRED MONITORING OF INJECTABLE TREATMENT

| Test | Frequency | CDC recommendations | Notes |
|--|--|----------------------------------|------------------------------|
| HIV (Ag/Ab & HIV 1 RNA assay | Baseline + Prior to each injection + when stopping CAB | Required | If positive, refer |
| Three site STI screening (syphilis, gonorrhea, chlamydia) | Baseline + Every 4 months (starting with 3rd injection) for MSM & TGW Every 6 months (starting with 5th injection) for heterosexual ly-active persons When stopping CAB (only for MSM, TGW) | Recommended | If positive – refer for care |
| Need to continue PrEP | Annually | Recommended if at continued risk | Discuss with patient |

TABLE 2b-ROUTINE REQUIRED MONITORING OF ORAL TREATMENT

| Test | Frequency | CDC Recommendations | Notes |
|---|--|---------------------|------------------------------------|
| <u>HIV Ag/Ab</u> | <u>Baseline + Every 3 months</u> | <u>Required</u> | <u>If positive, refer</u> |
| <u>HIV-1 RNA assay and assess for signs/symptoms of acute HIV infection</u> | <u>Every 3 months + when stopping PrEP</u> | <u>Required</u> | <u>If positive, refer</u> |
| <u>Three site STI screening (syphilis, gonorrhea, chlamydia)</u> | <u>Baseline + Every 3 months + when stopping PrEP for MSM & TGW</u> <u>Every 6 months for heterosexually-active persons</u> | <u>Recommended</u> | <u>If positive, refer for care</u> |

| | | | |
|--|---|---|--|
| <u>Serum creatinine</u> | <u>Baseline +</u> <u>Every 6 mo. If age ≥50 or eCrCL <90 mL/min at PrEP initiation</u> <u>Every 12 mo. If continuing PrEP</u> <u>+ When stopping PrEP</u> | <u>Recommended</u> | <u>If CrCL <60 mL/min, cannot use F/TDF</u> <u>If CrCL <30 mL/min, cannot use F/TAF</u> <u>If rapid decline in kidney function, consult nephrology</u> |
| <u>Weight, Lipid panel (if taking F/TAF)</u> | <u>Baseline, + Every 12 months</u> | <u>Recommended</u> | |
| <u>Hepatitis B screening</u> | <u>Baseline</u> | <u>Recommended</u> | <u>If positive – refer for care</u> |
| <u>Need to continue PrEP</u> | <u>Annually</u> | <u>Recommended if at continued risk</u> | <u>Discuss with patient</u> |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted infections.
- For injectable cabotegavir: the long drug “tail” of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug resistant strain of HIV during this time. To help patients safely discontinue CAB PrEP injections pharmacists should:
 - Re-educate patients about the tail and the risks during declining CAB levels
 - Assess ongoing risk/indications
 - If PrEP is indicated prescribe oral F/TDF or F/TAF beginning with 8 weeks after last injection
 - Educate about nPEP
 - Conduct HIV-1 RNA tests at each quarterly follow up visit after discontinuation of CAB injections and discuss the importance of keeping these follow up appointments

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: <https://cdphe.colorado.gov/living-with-hiv>
- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: <https://cdphe.colorado.gov/living-with-hiv>
- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.
- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.
- If a female patient becomes pregnant while on PrEP
- Usual care for any other issues, stress importance of routine primary care and health maintenance.

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

Non-Occupational Post-Exposure Prophylaxis (nPEP) is the use of antiretroviral drugs after a single high-risk event to decrease the risk of HIV seroconversion. nPEP must be started as soon as possible to be effective, and always within 72 hours of the possible exposure. This particular protocol addresses non occupational post-exposure prophylaxis (nPEP) only, those with occupational exposures are not eligible and should be referred for care.

Under this protocol, pharmacists may assess patients 13 and older for high-risk exposure to HIV and prescribe antiretroviral drugs if appropriate. Patients under 18 years of age require parental consent to access this Protocol. nPEP should only be provided for infrequent exposures.

If the pharmacy is not able to provide care to the patient, or if the patient does not qualify for care at the pharmacy, the patient should be referred to another provider. PEP providers in Colorado include the STD Clinic at Denver Public Health (303.602.3540) and local emergency departments (CDPHE to comment).

If the following criteria are met, antiretroviral agents in Table 3a are recommended:

- The exposure must have occurred within 72 hours
- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.
- Exposure to a source individual known to be HIV-positive. Exposure of:

- o Vagina
- o Rectum
- o Eye
- o Mouth
- o Other mucous membranes
- o Nonintact skin
- o Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

WITH

- o Blood
- o Semen
- o Vaginal secretions
- o Rectal secretions
- o Breast milk
- o Any body fluid visibly contaminated with blood
- Exposure types with the highest risk of transmission of HIV are:
 - o Needle sharing during injection drug use
 - o Percutaneous needle stick
 - o Receptive anal intercourse
- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 3a may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

Patients who should NOT be prescribed nPEP under this protocol and should be referred to primary care provider for further action:

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP

- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services **MUST** be contacted.

Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at <https://www.ccasa.org/gethelp/health-related-organizations/>
- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services **MUST** be contacted 1-844-CO-4-KIDS.

TABLE 3a – MEDICATION OPTIONS

Other FDA approved / CDC recommended medications or regimens can be used if they become available. Formulations cautions and dose adjustments for antiretroviral medications shall minimally follow the CDC guidelines and package insert information for all regimens.

| Medication | Age/Weight | Dose | Duration of Therapy | Notes |
|---|------------|--|---------------------|--|
| PREFERRED REGIMEN | | | | |
| emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic) PLUS raltegravir 400mg OR Dolutegravir 50mg | ≥ 13 years | Once daily #28 no refills Twice daily #56 no refills Once daily #28 no refills | 28 days | Dosing adjustments with renal dysfunction if CrCL <60 ml/min. Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then “alternative regimens” per CDC guidelines should be referenced and used. |

TABLE 4a – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.
- Ask the following screening question:

- o Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?

In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.
- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

| Test | Frequency | CDC recommendations | Notes |
|--|--|---------------------|--|
| HIV | Baseline + Post-exposure at week 4-6, and months 3 and 6 | Required | If positive, refer. |
| STI screenings (syphilis, gonorrhea, chlamydia) | Baseline | Recommended | If positive – refer for care |
| Serum creatinine | Baseline + @4-6 weeks. | Recommended | |
| ALT/AST | Baseline + @4-6 weeks. | Recommended | |
| Hepatitis B screening | Baseline + 6 mo | Recommended | If positive – refer. If negative and clinically appropriate, vaccinate |
| Hepatitis C screening | Baseline + 6 mo | Recommended | If positive - refer |
| Pregnancy | Baseline + @4-6 weeks. | Recommended | Pregnancy is not a contraindication to NPEP |

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed

- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Rule 17.

Referrals:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: <https://cdphe.colorado.gov/living-with-hiv>
- The patient should be referred immediately for guideline based follow-up HIV testing and care, and follow-up testing for STIs, Hepatitis C, and Hepatitis B.
- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: <https://cdphe.colorado.gov/living-with-hiv>
- If a patient tests positive for Hepatitis B or C, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: <https://cdphe.colorado.gov/living-with-hiv>
- Signs of symptoms of acute drug toxicities or serious side effects
- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.
- Usual care for any other issues, stress importance of routine primary care and health maintenance.

¹CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2021 update Clinical Practice Guideline. Available at: <https://stacks.cdc.gov/view/cdc/112360>

²USPTF. Preexposure Prophylaxis for the Prevention of HIV Infection US Preventive Services Task Force Recommendation Statement. JAMA. 2019;321(22):2203-2213. doi:10.1001/jama.2019.6390

³CDC. Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use or Other Nonoccupational Exposure to HIV – United States, 2016. Available at: <https://stacks.cdc.gov/view/cdc/38856>

APPENDIX D

MODEL SEXUAL MISCONDUCT DISCLOSURE STATEMENT

DISCLAIMER: This Model Sexual Misconduct Disclosure Statement is to be used as a guide only and is aimed only to assist the provider in complying with section 12-30-115, C.R.S., and the rules promulgated pursuant to this statute by the relevant regulator. As a provider in the State of Colorado, you are responsible for ensuring that you are in compliance with state statutes and rules. While the information below must be included in your Sexual Misconduct Disclosure Statement pursuant to section 12-30-115, C.R.S., you are welcome to include additional information that specifically applies to your situation and practice.

- A. Provider information, including, at a minimum: name, business address, and business telephone number.
- B. Pursuant to section 12-30-115, C.R.S., and the rules promulgated pursuant to this statute by the relevant regulator, a listing of any final convictions of or acceptances of guilty pleas by a court for a sex offense, as defined in section 16-11.7-102(3), C.R.S.

For each, the provider shall provide, at a minimum:

- 1. The date that the final judgment of conviction or acceptance of a guilty plea was entered;
 - 2. The nature of the offense or conduct that led to the final conviction or guilty plea;
 - 3. The type, scope, and duration of the sentence or other penalty imposed, including whether:
 - a. The provider entered a guilty plea or was convicted pursuant to a criminal adjudication;
 - b. The provider was placed on probation and, if so, the duration and terms of the probation and the date the probation ends; and
 - c. The jurisdiction that imposed the final conviction or issued an order approving the guilty plea.
- C. Pursuant to section 12-30-115, C.R.S., and the rules promulgated pursuant to this statute by the relevant regulator, a listing of any final agency action by a regulator that results in probationary status or other limitation on the provider's ability to practice, when the action is based in whole or in part on:
- 1. A conviction or acceptance of a guilty plea by a court for a sex offense, as defined in section 16-11.7-102(3), C.R.S., or a finding that the provider committed a sex offense, as defined in as defined in section 16-11.7-102(3), C.R.S.; OR
 - 2. A finding that the provider engaged in unprofessional conduct or other conduct that is grounds for discipline under the part or article of Title 12 of the Colorado Revised Statutes that regulates the provider's profession, where the failure or conduct is related to, includes, or involves sexual misconduct that results in harm to a patient or presents a significant risk of public harm to patients.
 - 3. For each, the provider shall provide, at a minimum:

- a. The type, scope, and duration of the agency action imposed, including whether:
 - (1) the regulator and provider entered into a stipulation;
 - (2) the agency action resulted from an adjudicated decision;
 - (3) the provider was placed on probation and, if so, the duration and terms of probation; and
 - (4) the regulator imposed any limitations on the provider's practice and, if so, a description of the specific limitations and the duration of the limitations.
- b. The nature of the offense or conduct, including the grounds for probation or practice limitations specified in the final agency action;
- c. The date the final agency action was issued
- d. The date the probation status or practice limitation ends; and
- e. The contact information for the regulator that imposed the final agency action on the provider, including information on how to file a complaint.

Sample Signature Block

I have received and read the sexual misconduct disclosure by [Provider Name] and I agree to treatment by [Provider Name].

Print Patient Name

Patient or Responsible Party's Signature

Date

If signed by Responsible Party (parent, legal guardian, or custodian), print Responsible Party's name and relationship to patient:

Print Responsible Party Name

Print Relationship to Patient

Provider Signature

Date

Appendix E

Colorado State Board of Pharmacy Statewide Protocol

Statin Therapy

This collaborative pharmacy practice statewide protocol authorizes qualified, Colorado-licensed, pharmacists ("Pharmacists") to provide pertinent assessment of patients with or at high-risk for cardiovascular (CV) events and prescribe HMG CoA reductase inhibitor therapy (henceforth known as "statin therapy") for the purpose of reducing the risk for new or recurrent CV events according to, and in compliance with, all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA approved medication(s) to eligible patients according to indications and contraindications recommended in current guidelines from the American Heart Association and American College of Cardiology (AHA/ACC) 1 or subsequent updated published guidelines recognized as the national standard of practice. Request for updates to this protocol shall be considered through the Board of Pharmacy rulemaking process.

Prior to prescribing and dispensing statin therapy per this protocol, the pharmacist must:

1. Hold a current license to practice pharmacy in Colorado
2. Be engaged in the practice of pharmacy
3. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist
4. Carry adequate professional liability insurance as determined by the Board
5. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.)
6. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00.

If services are provided in a pharmacy, the pharmacy shall ensure that appropriate space is available to provide counseling and ensure confidentiality.

Records:

- A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and laboratory test(s) ordered, and any test results.
- B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.
- C. Statin Therapy Protocol

Under this protocol, pharmacists may assess patients with or at high-risk for a CV event who are not currently on but in whom statin therapy is identified as a Class I recommendation according to AHA/ACC guidelines¹.

Eligibility Criteria: The pharmacist may consider and prescribe the patient statin therapy listed in Table I according to the following criteria:

1. High-risk primary prevention
 - a. 10-Year Atherosclerotic Cardiovascular Disease (ASCVD) Risk $\geq 20\%$ using the American College of Cardiology risk calculator (found at <http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/>) age 40-75; or
 - b. LDL ≥ 190 mg/dL tested using a fasting lipid panel, age 20-75
2. Primary prevention patients with diabetes mellitus
 - a. Type 2 diabetes mellitus (DM) age 40-75 as determined by patient report, medical records, or prescription history.
3. Secondary prevention
 - a. Prior history of acute myocardial infarction, acute coronary syndrome, stable or unstable angina, coronary or arterial revascularization by coronary artery bypass graft (CABG) surgery and /or stenting, non-cardioembolic ischemic stroke, transient ischemic attack, aortic aneurysm, or peripheral artery disease all stemming from atherosclerotic origins, as confirmed by patient report, medical records, or prescription history.

Ineligibility Criteria: Patients who should NOT be prescribed statin therapy under this protocol and should be referred to primary care provider for further action:

1. Patients who have a history of serious statin-associated side effects defined as a serum creatine kinase elevation >3 times the upper limit of normal, documented rhabdomyolysis from statin therapy, or hepatic transaminase elevations 3 times the upper limit of normal during prior treatment with statin therapy.
2. Patients who have active liver disease defined by medical history or by hepatic transaminases greater than 3 times the upper limit of normal.
3. Women who are pregnant or are of childbearing age and not using highly effective forms of contraception.
4. Patients with end stage renal disease (ESRD) or who are undergoing hemodialysis or peritoneal dialysis.
5. Patients with severe hypertriglyceridemia (fasting triglycerides ≥ 1000 mg/dL).

TABLE 1 – MEDICATION OPTIONS

Other FDA approved and guideline recommended medications or regimens can be used if they become available.

Formulations cautions and dose adjustments for statin medications shall minimally follow the AHA/ACC guidelines and package insert information for all regimens.

Pharmacist must screen for potential statin drug/drug interactions with patient's other known medications. If interactions are identified, appropriate selection of a safe statin regimen and counseling should be performed to mitigate risk.

| Patient Category | Medication and Dosage | Renal Adjustment | Frequency |
|---|------------------------------|--|----------------------------------|
| High risk primary prevention* or secondary prevention | Atorvastatin 40-80 mg | No adjustment needed | Once daily |
| | Rosuvastatin 20-40 mg | CrCl < 30 ml/min/1.73m²: 5-10 mg or consider atorvastatin 40-80mg | Once daily |
| Primary prevention patients with DM and not "high Risk" | Atorvastatin 10-20 mg | No adjustment needed | Once daily |
| | Fluvastatin 40 mg | No adjustment needed | Twice daily |
| | Fluvastatin XL 80 mg | No adjustment needed | Once daily |
| | Lovastatin 4080 mg | CrCl <30 ml/min: 20 mg max dose | Once daily in evening |
| | Pitavastatin 14 mg | GFR 15-59 ml/min/1.73m²: 1-2 mg | Once daily |
| | Pravastatin 4080 mg | Severe impairment: 10 mg | Once daily in the evening |
| | Rosuvastatin 5-10 mg | No adjustment needed | Once daily |
| | Simvastatin 20-40 mg | Severe impairment: start at 5 mg (titrate as needed up to 20mg daily) | Once daily in the evening |
| <p>* High risk primary prevention patients include: baseline LDL-C ≥190 mg/dL, diabetes age 40-75 years with LDL-C < 190 mg/dL and multiple ASCVD risk factors, or age 40-75 with LDL-C 70-189 mg/dL and 10-year ASCVD risk ≥20%.</p> | | | |

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

| Test | Frequency | Guideline recommendations | Notes |
|----------------------------------|--|---|--|
| Fasting Lipid Panel (FLP) | Every 3-12 months | Get FLP at baseline and then 4-12 weeks after therapy initiation, then every 3-12 months as needed to assess adherence and improvement | <p>Guidelines allow for non-fasting lipid panels for baseline LDL-C but recommend fasting lipid panels for follow-up monitoring.</p> <p>Point of care (POC) testing acceptable.</p> <p>Baseline labs from PCP can be accepted if within 3 months of statin initiation.</p> |
| ALT / LFTs | Baseline required - Ordered by pharmacist or accepted documentation from PCP within 3 months of statin initiation | Routine monitoring not needed. | Patients presenting with signs or symptoms suspicious of liver disease should be referred for medical evaluation |
| Renal function | Baseline and yearly | Not in guidelines | <p>Yearly monitoring is recommended to determine if dose adjustment is necessary (as for all medications).</p> <p>This will be ordered by pharmacists, or communicated to patient for ordering and follow up by primary care provider.</p> |

Counseling (at minimum):

- The importance of medication adherence with relation to efficacy of statin therapy and reduction in CV event risk, and what to do if patient misses a dose.
- Importance of therapeutic lifestyle changes in reducing lipids and CV risk.
- Proper use of medication, storage, dosage, schedule, and potential common and serious side effects (and how to mitigate).
- Signs/symptoms of myalgia and liver dysfunction, educate that side effects are not common

- Potential food and medication interactions (primarily with lovastatin and simvastatin)
- The necessity of follow up care with a primary care provider for usual care and lipid testing at least yearly.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in Rule 17.

Referrals to primary care provider:

- Prior history of statin use with noted severe intolerance. Pharmacist encouraged to work collaboratively with PCP on options.
- On therapy, if patient experiences moderate to severe statin associated muscle symptoms that do not resolve with stopping medication
- On therapy, if patient experiences symptoms consistent with muscle weakness or rhabdomyolysis (dark brown urine with severe muscle symptoms) – patient should stop statin and be referred.
- On therapy, if the patient develops symptoms suggestive of liver disease (severe abdominal pain, yellow-colored eyes or skin) – patient should stop statin and be referred.
- On therapy if patient becomes pregnant – patient should stop statin and be referred.
- Suboptimal response to maximum tolerated statin therapy – patient continues statin and referred for further workup.

¹ Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC Jr, Sperling L, Virani SS, Yeboah J. 2018AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):e285e350. doi: 10.1016/j.jacc.2018.11.003. Epub 2018 Nov 10. Erratum in: J Am Coll Cardiol. 2019 Jun25;73(24):3237-3241.

PMID: 30423393. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines | Journal of the American College of Cardiology (jacc.org)

APPENDIX F

Your Rights and Protections Against Surprise Medical Bills

When you get emergency care or get treated by an out-of-network provider at an in-network hospital or ambulatory surgical center, you are protected from surprise billing or balance billing.

What is “balance billing” (sometimes called “surprise billing”)?

When you see a doctor or other health care provider, you may owe certain out-of-pocket costs, like a copayment, coinsurance, or deductible. You may have additional costs or have to pay the entire bill if you see a provider or visit a health care facility that isn’t in your health plan’s network.

“Out-of-network” means providers and facilities that haven’t signed a contract with your health plan to provide services. Out-of-network providers may be allowed to bill you for the difference between what your plan pays and the full amount charged for a service. This is called “balance billing.” This amount is likely more than in-network costs for the same service and might not count toward your plan’s deductible or annual out-of-pocket limit.

“Surprise billing” is an unexpected balance bill. This can happen when you can’t control who is involved in your care—like when you have an emergency or when you schedule a visit at an in-network facility but are unexpectedly treated by an out-of-network provider. Surprise medical bills could cost thousands of dollars depending on the procedure or service.

You’re protected from balance billing for:

Emergency services

If you have an emergency medical condition and get emergency services from an out-of-network provider or facility, the most they can bill you is your plan’s in-network cost-sharing amount (such as copayments, coinsurance, and deductibles). You can’t be balance billed for these emergency services. This includes services you may get after you’re in stable condition, unless you give written consent and give up your protections not to be balance billed for these post-stabilization services.

If you believe you’ve been wrongly billed by a healthcare provider, please contact the State Board of Pharmacy at 303-894-7800 or dora_pharmacyboard@state.co.us.

Visit the CMS No Surprises Act website (<https://www.cms.gov/nosurprises/consumers>) for more information about your rights under federal law.

Review section 12-30-112, C.R.S., for more information about your rights under Colorado state law.

Certain services at an in-network hospital or ambulatory surgical center

When you get services from an in-network hospital or ambulatory surgical center, certain providers there may be out-of-network. In these cases, the most those providers can bill you is your plan's in-network cost-sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, assistant surgeon, hospitalist, or intensivist services. These providers can't balance bill you and may not ask you to give up your protections not to be balance billed.

If you get other types of services at these in-network facilities, out-of-network providers can't balance bill you, unless you give written consent and give up your protections. You're never required to give up your protections from balance billing.

You also aren't required to get out-of-network care. You can choose a provider or facility in your plan's network.

When balance billing isn't allowed, you also have these protections:

- You're only responsible for paying your share of the cost (like the copayments, coinsurance, and deductible that you would pay if the provider or facility was in-network). Your health plan will pay any additional costs to out-of-network providers and facilities directly.
- Generally, your health plan must:
 - Cover emergency services without requiring you to get approval for services in advance (also known as "prior authorization").
 - Cover emergency services by out-of-network providers.
 - Base what you owe the provider or facility (cost-sharing) on what it would pay an in network provider or facility and show that amount in your explanation of benefits.
 - Count any amount you pay for emergency services or out-of-network services toward your in-network deductible and out-of-pocket limit.

If you believe you've been wrongly billed by a healthcare provider, please contact the State Board of Pharmacy at 303-894-7800 or dora_pharmacyboard@state.co.us. The federal phone number for information and complaints is: 1-800-985-3059.

Visit www.cms.gov/nosurprises/consumers for more information about your rights under federal law.

Visit <https://dpo.colorado.gov/Pharmacy> for more information about your rights under Colorado state law, pursuant to section 12-30-112, C.R.S.

Editor's Notes

History

Rules 2.01.10; 2.01.30; 3.00.50; 3.00.70, 6.00.20; 6.00.30; 6.00.40; 8.00.10; 11.04.20; 14.03.10 eff. 07/30/2007.

Rules 8.00.10; 11.04.10; 20.00.00 eff. 09/30/2007.

Rule 4.00.00 eff. 11/30/2007.

Rules 3.01.20, 10.00.00 eff. 03/01/2008.

Rules 5.01.31; 15.01.11; 15.01.12; 15.09.11; 15.09.14; 22.00.00 eff. 05/30/2008.

Rules 4.02.00 (c), 21.00.00, 23.00.00 eff. 06/30/2008.

Rules 1.00.00, 2.00.00, 3.00.00, 5.00.00, 7.00.00, 11.00.00, 12.00.00, 14.00.00 eff. 11/30/2008.

Rule 15.09.11 eff. 01/31/2009.

Rules 6.00.30, 11.06.00, 22.00.00 eff. 03/02/2009.

Rule 9.00.00 eff. 04/30/2009.

Rules 5.00.55, 5.01.31(a), 6.00.20(f), 14.00.40, 15.01.17, 15.01.18, 15.08.19(f), 15.09.11(d), 15.09.15, 15.09.19, 15.09.20(g-h), 15.09.23, 15.09.24, 15.10.10, 16.00.20(d), 19.01.10(b), 19.01.30(a) eff. 12/30/2009.

Rules 4.00, 18.00 eff. 03/17/2010.

Rules 3.00.80 – 3.00.90; 5.00.55; 15.01.12; 19.00.00 – 19.01.50. Rule 22.00.00 repealed eff. 07/15/2010.

Rules 1.00.21, 5.01.31(e), 5.01.50 eff. 08/30/2010.

Rules 5.00.55, 21.11.10 (a), 21.21.70 (a) eff. 11/14/2010.

Rules 1.00.18, 2.01.50 – 2.01.53, 3.00.50 – 3.00.51, 5.00.50, 5.00.60, 5.01.31.a, 11.04.10, 15.01.11, 15.09.11.e eff. 06/14/2011.

Rules 3.01.24, 4.00.00, 11.04.20, 11.04.30, 21.00.00 - 21.11.20, 23.00.00 eff. 04/14/2012.

Rule 14.00.10 eff. 05/15/2012.

Entire rule eff. 01/01/2013. Rule 17.00.00 repealed eff. 01/01/2013.

Rules 3.00.21 – 3.00.22, 3.00.55, 3.00.90.e.(4), 3.01.20.c, 3.01.30, 3.01.32, 3.01.34, 4.00.10.f, 4.00.20, 5.01.31.a.(1)(C), 15.10.14.a, 23.00.90 eff. 09/14/2013.

Rules 2.01.10, 3.00.25, 3.00.91, 5.00.15, 6.00.30, 10.00.00, 11.03.00, 11.07.10, 14.00.05.k-l, 14.00.80.e.(2), 14.00.80.j, 16.00.00, 18.00.00, 20.00.00, 21.00.20, 21.10.80, 21.11.00.a.(12), 21.11.10.c, 21.20.20, 21.20.30.b(14), 21.21.40.c, 21.21.70.c, 21.22.00.b(1), 23.00.30, 23.00.50, 23.00.65, 23.00.70, eff. 10/15/2014.

Rules 3.00.22, 3.00.81.l-o, 3.00.82-3.00.84, 3.00.85.a(3), 3.00.86, 3.00.88.a(2), 3.00.88.b(10), 4.06.00, 6.00.10-6.00.20, 6.00.40.a, 6.00.50, 6.00.60.a, 6.00.60.b.10, 6.00.70.a, 6.00.90.b, 6.01.10.a, 19.01.40.c, 21.00.10, 21.00.20.b, 21.10.60.b, 21.10.80.b(4), 21.11.10.a(5), 21.11.10.c(9), 21.20.10.d, 21.20.20.b(2)(a), 21.20.25.b, 21.20.70.f, 21.20.90.b-c, 21.21.10.b, 21.21.70.a(6), 21.21.70.c(10), 23.00.40.y-z, 23.00.70.h-j eff. 09/14/2015.

Rules 3.00.21, 3.00.27, 19.01.10(1), 21.00.20, 21.11.20.d, 21.20.16, 21.20.20.b.(2), 21.20.60.b, 21.20.60.e, 21.21.90.d eff. 03/16/2016.

Rules 3.00.20, 3.00.22 e, 3.00.81 g, 3.00.84, 3.01.10 d, 4.00.10, 4.00.25, 4.05.00, 5.00.15 d, 5.01.31, 6.00.20 e, 7.00.10, 8.00.10, 14.00.80 i-k, 19.01.10 b.(2), 20.00.80 a.1, 21.00.20, 21.00.30, 21.20.20 b, 27.00.00, 28.00.00 eff. 11/14/2016. Rule 10.00.51 repealed eff. 11/14/2016.

Rule 17 eff. 03/17/2017. Rule 18 repealed eff. 03/17/2017.

Rules 3.01.10 d, 7.00.30 b.4, 21.00.20, 21.00.30, 23.00.10, 23.00.70 eff. 11/14/2017. Rules 1.00.15, 5.00.55 a.(6) repealed eff. 11/14/2017.

Rules 3.05.00, 5.01.31 m, 5.01.31 r, 5.01.40 a, 5.01.50 a-f, 11.03.05, 11.04.10, 11.06.10 j, 14.02.30 d, 20.00.90 c, 20.01.00 a.2.iv, 21.00.20 d.ii, 21.20.70 g, 25.00.12 d-e, 25.00.14 c-d, 25.00.16 e eff. 09/17/2018.

Rules 1.00.24, 2.01.50, 2.01.52, 2.01.53, 2.01.56, 2.01.80, 3.00.23, 3.00.30, 3.05.10-3.05.30, 3.05.80, 7.00.30 c, 11.03.00 a, 11.07.10 a, 14.00.05 m, 14.00.40 f.1, 14.00.80 e, 15.01.11 a.(8)(i), 15.01.11 a.(9), 15.09.14 a, 19.01.10 b.-c, 23.00.10, 23.00.70, 29.00.00 eff. 11/30/2019.

Rule 30.00.00 emer. rule eff. 05/01/2020; expired 08/28/2020.

Rules 17.00.10, 17.00.30 a.7, 17.00.50 b.2, 17.00.70, 17.00.80, 17.01.00, 17.02.00 a, 17.03.00 b, 17.04.00 eff. 05/15/2020. Rule 6.00.00 repealed eff. 05/15/2020.

Rule 30.00.00 eff. 08/30/2020. Rule 3.04.00 repealed eff. 08/30/2020.

Rules 2.01.20, 3.00.81 a, 3.01.22 b, 5.00.40, 5.00.50 a, 7.00.30 b, 10.00.60, 11.08.00, 11.08.50, 14.00.05 b, 14.00.40 b.-c, 14.05.11, 15.05.20, 15.01.11 b.-d, 15.01.14 a-b, 15.01.17, 17.00.50 c, 24.00.50, Appendix C eff. 11/14/2020.

Rule 19.00.00 emer rule eff. 11/19/2020.

Rule 1.00.25, Appendix D eff. 12/30/2020.

Rules 5.01.31 j-k, 17.00.10 d, 19.01.10, 19.01.20, 19.01.30 a, 19.01.40 a.(5)-(9), 19.01.50 a.(3) eff. 03/17/2021.

Rule 1.00.25 E-F eff. 05/15/2021.

Rules 1.00.18, 1.00.24, 2.01.10 d-f, 2.01.20, 3.00.21, 3.00.22, 3.03.10 a(2), 3.03.10 a(7), 3.03.10 b(2), 5.00.01, 5.00.10, 5.00.17, 5.00.19, 5.00.40, 5.00.50, 5.00.55 b, 5.00.60, 7.00.30, 9.00.10 e, 14.00.05, 14.00.80 e(1), 15.01.00 a, 15.02.10, 15.09.11, 15.09.12 c, 15.09.14 a, 15.10.10 l, 17.00.10, 21.00.10, 21.00.20, 21.11.10 c, 21.21.70 a, 23.00.10 n, 23.00.30, 23.00.40, 23.00.50, 23.00.90 a.2, 23.00.90 c, 29.00.50, Appendix C eff. 11/30/2021.

Rules 32.00.00, 33.00.00 emer. rules eff. 09/29/2022.

Rules 3.00.22, 4.00.30 e, 4.00.40 e.-f, 5.00.19 a, 7.00.10 a, 14.00.05 l.-o, 14.00.40 f.(1), 14.00.80 e, 16.00.10, 16.00.20 d.(2), 16.00.80, 16.02.00, 16.02.01, 16.02.03, 17.00.70, 17.00.80, 17.01.00 a, 25.00.10, 25.00.12 a, 25.00.18, 25.00.24 a, 31.00.00, 33.00.00, 34.00.00, Appendices A, C, E, F eff. 11/30/2022.

Rules 5.00.01 g, 5.00.21 emer. rules eff. 07/20/2023.

Rules 5.00.01 g, 5.00.21 eff. 09/14/2023.

Rule 33.00.00 emer. rule eff. 10/01/2023.

Rule 33.00.00 eff. 11/14/2023.

Rules 1.00.25, 2.01.20, 2.01.50, 3.00.51, 5.00.01, 5.00.21, 5.00.60, 5.01.31, 5.01.40, 7.00.10, 11.03.00, 11.06.10, 11.06.30-11.06.50, 11.10.00, 11.11.00, 12.00.32, 14.00.20, 14.00.40, 14.00.60, 14.00.80, 14.02.30, 17.00.10, 17.00.70, 17.00.80, 19.01.10, 20.01.20, 21.00.30, 21.10.00-21.10.40, 21.10.60-21.10.90, 21.11.00, 21.11.10, 21.11.20, 21.11.25, 21.20.10-21.20.23, 21.20.30, 21.20.50-21.20.90, 21.21.10, 21.21.20-21.21.80, 21.22.00, 21.22.10, 23.00.70, 26.00.10, 26.00.20, 27.00.10, 27.00.20, 27.00.40, 31.06.00, Appendix A eff. 11/30/2023.
Rules 2.01.58, 3.01.30-3.01.34, 14.00.30, 14.00.50, 21.10.70, 21.10.90, 21.11.00, 21.11.10, 21.20.40, 30.00.00, 32.00.00, 33.00.00 repealed eff. 11/30/2023.

Rules 14.03.00 a.(13), 14.03.10 c.(12), 14.03.10 e, 14.03.30 eff. 03/16/2024.

Annotations

Rules 33.00.00 D. and 33.00.00 E. (adopted 09/29/2022) were not extended by Senate Bill 23-102 and therefore expired 05/15/2023.