Basis and Purpose: The purpose of the amendment to Board Rule 3.00.20 is to implement HB 16-1095 which allows for the dispensing of an additional bottle of a prescription eye drop to a patient under certain conditions. The purpose of the amendment to Board Rule 3.00.22 is to make a technical amendment on the advice of the Office of Legislative Legal Services. The purpose of the amendment to Board Rule 3.00.81 is to include out-of-state entities as part of the definition of "Nonprofit Entity" for the purpose of prescription drug donation. The purpose of the amendment to Board Rule 3.00.84 is to clarify a condition in which a drug may be donated and re-dispensed. The purpose of the amendment to Board Rule 3.01.00 is to implement HB 16-1152 which allows pharmacies owned and operated by the Colorado Department of Corrections ("DOC") to distribute drugs, without limitation, to other pharmacies owned and operated by the DOC. The purpose of the amendments to Board Rule 4.00.10 is to define both "enrollment" and "disenrollment" from a Board-approved school or college of pharmacy. The purpose of the addition of Board Rule 4.00.25 is to require actively licensed pharmacy interns to report to the Board upon meeting the definition of "disenrollment" from a Board-approved school or college of pharmacy. The purpose of the amendment to Board Rule 4.05.00 is to provide a timeframe for reporting name and electronic mail address changes and to eliminate the burden upon a Board licensee to report to the Board any change in location of employment. The purpose of the amendment to Board Rule 5.00.15 is to implement HB 16-1324 which allows an in-state or nonresident pharmacy to distribute compounded products to Colorado-based veterinarians for office use under certain limitations and conditions. The purpose of the amendments to Board Rule 5.01.31 is to eliminate the minimum space requirement for a pharmacy satellite used solely for the purpose of drug storage and to specify certain conditions and limitations to such satellites. The purpose of the amendment to Board Rule 6.00.20 is to make a technical amendment on the advice of the Office of Legislative Legal Services. The purpose of the amendments to Board Rule 7.00.10 is to clarify the reporting requirements of a pharmacist manager to the Board. The purpose of the amendment to Board Rule 8.00.00 is to clarify the prescription labeling requirements of prescriptions that are dispensed by way of central prescription processing. The purpose of the amendments to Board Rule 10.00.51 is to eliminate the burden of an in-state pharmacy or hospital other outlet to report to the Board either the supplying of an emergency kit to an authorized entity or any changes with respect to ownership or consultant pharmacist involving an emergency kit. The purpose of the amendments to Board Rule 14.00.80 is to clarify the reporting requirements of an other outlet consultant pharmacist to the Board. The purpose of amending Board Rule 19.01.10 is to clarify the meaning of the word "current" when referencing a basic cardiopulmonary resuscitation (CPR) certification. The purpose of the amendment to Board Rule 20.00.80 is to clarify the prescription labeling requirements of prescriptions that are dispensed by way of central prescription processing. The purpose of the amendments to Board Rules 21.00.20 and 21.00.30 is to implement HB 16-1324 which allows an in-state or nonresident pharmacy to distribute compounded products to Colorado-based veterinarians for office use under certain limitations and conditions. The purpose of the amendments to Board Rule 21.20.20 is to clarify the definition of low risk compounded sterile products. The purpose of the addition of Board Rule 21.30.00 is to define and, by reference to the United States Pharmacopeia/National Formulary Chapter 800, to specify the standards for handling hazardous drugs in outlet settings to promote patient/worker safety and environmental protection. The purpose of the amendments to Board Rule 27.00.00 is to eliminate the minimum space requirement for a satellite used solely for the purpose of drug storage in a hospital satellite pharmacy setting and to specify certain conditions and limitations to such satellites. The purpose of Board Rule 28.00.00 is to implement SB 16-062 which, among other functions, specifies under what conditions Board matters are referred to the Veterinary Pharmaceutical Advisory Committee.

Authority for Promulgation of Rules: Sections 10-16-104, 12-42.5-101, 12-42.5-104.5, 12-42.5-105, 12-42.5-106(2) and (3), 12-42.5-118, 12-42.5-118.5, 12-42.5-133, 12-42.5-603 and 24-4-103, C.R.S.

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 CRS 12-42.5-123.

(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 (3) 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) 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 CRS 12-42.5-118.5(5)(b) must comply with the requirements of Rules 11.00.00 and 21.00.00.

3.00.22 The dispensing of an opiate antagonist, as described in Rule 3.00.21, by a pharmacist shall not constitute unprofessional conduct pursuant to CRS 12-42.5-123 if he or she dispensed the opiate antagonist in good faith pursuant to an order or standing orders and protocols issued to or for the following:

a. A person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event; or

b. A family member, friend, or other 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; or

c. An employee or volunteer of a harm reduction organization; or

d. A first responder.

e. For the purpose of this Rule ~~3.00.20~~ 3.00.22, the following definitions apply:

1) "First responder" means a peace officer, firefighter, or volunteer firefighter.

2) "Harm reduction organization" means an organization that provides services, including medical care, counseling, homeless services, or drug treatment, to individuals at risk of experiencing an opiate-related drug overdose event or to the friends and family members of an at-risk individual.

3) "Opiate-related drug overdose event" means an acute condition, including but not limited to, a decreased level of consciousness or respiratory depression resulting from the consumption or use of a controlled substance, or another substance with which a controlled substance was combined, and that a layperson would reasonably believe to be an opiate related drug overdose event that requires medical attention.

4) "Protocol" means a specific written plan, as maintained in a uniform and readily retrievable manner for the purpose of inspection at the prescription drug outlet for at least two (2) years from the date of the latest dispensing transaction related to protocol, for a course of medical treatment containing a written set of specific directions created by a physician, group of physicians, hospital medical committee, pharmacy and therapeutics committee, or other similar practitioners or groups of practitioners with expertise in the use of opiate antagonists.

5) "Standing order" means a prescription order, as maintained in a readily retrievable manner for the purpose of inspection at the prescription drug outlet for at least two (2) years from the date of the latest dispensing transaction related to order, written by a practitioner that is not specific to and does not identify a particular patient.

f. Each prescription drug outlet shall maintain, in a uniform and readily retrievable manner for at least two (2) years from the date of latest transaction related to a standing order, the following record detailing the dispensing of a non-controlled substance opioid antagonist pursuant to a 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, or harm reduction organization receiving the drug;**

2) **The full address of the first responder 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.**

3.00.81 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. An automated cassette shall not be used for schedule II controlled substances.**

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~~ve~~ 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.**

3.00.84 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 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 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 do not bear an expiration date at least six months or more from the date of return or donation~~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.**

3.01.00 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 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 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 12-42.5-118((~~(~~15)(b), C.R.S; ~~and~~**

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.

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.

~~f~~-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.

~~g~~- 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.

~~h~~j. For the purposes of this rule 4.00.00, "manufacturer" means a manufacturer of prescription drugs which is registered by the Board.

~~i~~k. "Pharmacist" means an individual licensed by this state to engage in the practice of pharmacy.

~~j~~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.

~~k~~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 30 days of meeting the definition of "Disenrollment" as defined in Rule 4.00.10(f) from a Board-approved school or college of pharmacy.

4.05.00 License Changes.

a. **Name change.** A licensee shall report a name change and provide appropriate supporting documentation within 30 days of such change~~The Board records shall reflect a name change that has been appropriately reported. When a licensee's name changes, a duplicate license will not be required in the new name~~. If the licensee wishes ~~a copy of the~~to obtain a new wall license with the new name, the licensee shall pay the requisite fee.

b. **Change of ~~employment or~~ residential and electronic mail address. All pharmacists and interns shall notify the Board in writing within 30 days of any ~~change of location of employment or~~ 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.**

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 (2) 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.

5.01.31 Within every prescription drug outlet as defined in CRS 12-42.5-102(35), there shall be one area designated as the principal compounding/dispensing area. In addition to the principal compounding/dispensing area there may be ~~one or more~~ satellite compounding/dispensing areas and drug storage areas ("satellites") which are located ~~in~~ at the same ~~building~~ 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 ~~areas~~ 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. ~~(1)~~ Any room ~~or rooms~~ included within or adjacent to the principal compounding / dispensing area that ~~are~~ is separated from the principal compounding / dispensing area by a door must meet the following:

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

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

~~(3)~~ ~~(C)~~ 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~~b~~. 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.

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

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

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

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

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

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

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

hd. 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.

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

jf. If refrigerated drugs are stored in the principal compounding/dispensing area or in any satellite, there shall be a refrigerator, dedicated to storing only drugs, meeting the compendia requirements and with an accurate thermometer in the refrigerator. The temperature of which shall be maintained between two and eight degrees Celsius (2 and 8 degrees C.) or thirty-six and forty-six degrees Fahrenheit (36 and 46 degrees F.). The temperature shall be ~~either manually or~~ 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.

kg. If frozen drugs are stored in the principal compounding/dispensing area or in any satellite, there shall be a freezer, dedicated to storing only drugs, meeting the compendia requirements and with an accurate thermometer in the freezer. The temperature of which shall be maintained between twenty-five degrees below zero and ten degrees below zero Celsius (– 25 and – 10 degrees C.) or thirteen degrees below zero and fourteen degrees Fahrenheit (– 13 and 14 degrees F.). The temperature shall be either manually or 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.

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

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

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

(3) Board rules;

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

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

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

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

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

nk. 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~~l~~. 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~~m~~. 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~~n~~. 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.

6.00.20 Drug therapy management requirements for all practice settings.

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

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

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

d. At a minimum, the written agreement for carrying out drug therapy management between 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 6.00.10 ~~b and~~ c and d, provided the protocol complies with 6.00.10 ~~d~~e, and the pharmacists performing these functions are qualified as set forth in section 6.00.30 and are working pursuant to a written agreement with an appropriately qualified prescriber.

f. Filing requirements.

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

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

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

7.00.10 Reporting Violations. The pharmacist manager of a prescription drug outlet shall report to the Board, in writing, within the timelines set forth ~~in the relevant rules and statutes, the following violations of the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act~~ below:

a. Diversion, theft or 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 24 hours 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.

b. Security breaches within the pharmacy or pharmacy area of the establishment within 10 days of discovery.

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

d. Any pharmacist working in the pharmacy who is impaired due to the use of alcohol or drugs, or a pharmacist with a mental or physical impairment which affects his ability to perform his job competently. In such instance the report shall be submitted to the Board immediately upon discovery.

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

8.00.00 ADVERTISING.

8.00.10 Labels. At least~~Only~~ one address shall appear on a prescription label and that shall ~~be~~ 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.

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 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 (60). Of the 60, twelve (12) may be controlled substances. The kit may contain no more than thirty (30) doses of any separate drug dosage form or strength for each drug. The container size for each drug shall be limited to unit dose or unit of issue packaging.

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

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

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

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

b. **The date of sealing of the kit;**

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

d. **In the case of a Long-Term Care Facility, 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.**

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

~~**Notification must be repeated, within 30 days:**~~

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

~~**or**~~

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

10.00.60 **Inspection. A pharmacist employed by the prescription drug outlet or hospital other outlet providing the kit or that pharmacist's designee shall inspect and**

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

10.00.70 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 72 hours after being notified that the kit was opened and the drug was used. The order shall indicate the total number of doses administered. The order shall be assigned a serial number and the order shall be retained as required by 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.

14.00.80 Consultant pharmacist.

a. A consultant pharmacist shall either:

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

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

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

c. A consultant pharmacist shall annually review the protocols for compliance with this 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; and

(h) Ambulatory Surgical Centers.

(2) Community clinics, federally qualified health centers, rural health clinics, colleges, acute treatment units, telepharmacies, 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 considered to run from January 1 through December 31.

(b) Every other week if more than 2,500 but less than 7,501 dispensing units are dispensed in a calendar year; A calendar year is considered to run from January 1 through December 31.

(c) Each week if 7,501 dispensing units but less than 12,501 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

(d) Twice each week if 12,501 dispensing units but less than 25,001 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.

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

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

h. The consultant pharmacist is responsible for ensuring all prescription drugs obtained by the other outlet are procured from an individual or entity registered b the 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 Board Rule 21.00.00 when compounding non-sterile and sterile products.

k. The consultant pharmacist shall be responsible for reporting diversion, theft or 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 24 hours 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.

14.00.80 Consultant pharmacist.

a. A consultant pharmacist shall either:

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

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

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

c. **A consultant pharmacist shall annually review the protocols for compliance with this 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; and**

(h) **Ambulatory Surgical Centers.**

(2) **Community clinics, federally qualified health centers, rural health clinics, colleges, acute treatment units, telepharmacies, 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 considered to run from January 1 through December 31.**

(b) **Every other week if more than 2,500 but less than 7,501 dispensing units are dispensed in a calendar year; A calendar year is considered to run from January 1 through December 31.**

(c) **Each week if 7,501 dispensing units but less than 12,501 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.**

(d) **Twice each week if 12,501 dispensing units but less than 25,001 dispensing units are dispensed in a calendar year. A calendar year is considered to run from January 1 through December 31.**

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

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

h. **The consultant pharmacist is responsible for ensuring all prescription drugs obtained by the other outlet are procured from an individual or entity registered b the 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 Board Rule 21.00.00 when compounding non-sterile and sterile products.**

k. **The consultant pharmacist shall be responsible for reporting diversion, theft or 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 24 hours 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.**

19.00.00 ADMINISTRATION.

19.01.00 Vaccines and Immunizations.

19.01.10 Qualifications.

a. A pharmacist certified in immunization, or pharmacy intern under the supervision of a pharmacist certified in immunization, may administer vaccines and immunizations per authorization of a physician. 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.

b. 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 20 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. Proof of completion of this training shall be posted at the pharmacist's or pharmacy intern's main practice location(s).

(2) The pharmacist or pharmacy intern holds a current basic cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or a basic cardiac life support certification. 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 pharmacist's main practice location.

(3) The vaccines are administered in accordance with CDC guidelines.

(4) The prescription drug outlet shall have a current version available, either in hard copy or electronically available, of the CDC reference "Epidemiology and Prevention of Vaccine-Preventable Diseases".

20.00.80 Prescription Labeling.

a. Prescriptions shall be labeled with all information required by CRS 12-42.5-121. In addition, the following shall be included on the label of any prescription dispensed via central processing:

1. The name and address of ~~either~~ 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.

21.00.20 Casual Sales/Distribution of Compounded Products.

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

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

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

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

(4) Hospital other outlets registered and located in Colorado.

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

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

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

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

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

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

e. 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 a companion animal'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.

~~c~~f. **Except as provided under CRS 12-42.5-118(15)(a), (b)(I) and (b)(II), the amount of compounded drug product a prescription drug outlet compounds and distributes shall be no more than ten (10) percent of the total number of drug dosage units the prescription drug outlet dispenses and distributes on an annual basis. An in-state compounding prescription drug outlet registered pursuant to CRS 12-42.5-117(9) may distribute compounded product pursuant to CRS 12-42.5-118(15)(a), (b)(I) and (II). All prescription drug outlets shall comply with all applicable federal laws and rules pertaining to the distribution of controlled substance preparations.**

~~d~~g. **The distributing prescription drug outlet or compounding prescription drug outlet must retain the following information on a current basis for each practitioner, hospital prescription drug outlet or hospital other outlet or, when allowable, each prescription drug outlet, to whom it distributes compounded products:**

(1) Verification of practitioner's license, or hospital prescription drug outlet's or hospital other outlet's registration; and

(2) Verification of practitioner's or hospital prescription drug outlet's or hospital other outlet's current Drug Enforcement Administration registration, if controlled substances are distributed;

~~e~~h. **Labeling of compounded products which are distributed shall comply with rule 21.11.10(c) or (d) or 21.21.70(c) or (d), whichever is applicable.**

~~f~~i. **Records of distribution shall comply with rule 11.07.10 or 11.07.20, whichever is applicable.**

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. Companion animal: An animal, other than a food animal, as defined by the Colorado Board of Veterinary Medicine.

~~d~~e. Component (ingredient): Any substance which is contained in a compounded preparation.

~~e~~f. Compounding:

(1) The preparation, mixing, or assembling, of one or more active ingredients with one or more other substances, or the assembling of a finished device:

(a) Formulated for use on or for the patient as the result of a practitioner's prescription drug order, chart order, or initiative, based on the relationship between the practitioner, patient, and pharmacist in the course of professional practice; or

(b) For the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; or

(c) In anticipation of prescription orders based on routine, regularly-observed prescribing patterns.

(2) Compounding does not include the preparation of copies of commercially available drug products. Compounded preparations that produce, for the patient, a significant difference between the compounded drug and the comparable commercially available drug product as determined, by the prescriber, as necessary for the medical best interest of the patient are not copies of commercially available products. "Significant differences" may include, but are not limited to, the removal of a dye for medical reasons (such as allergic reaction), changes in strength, and changes in dosage form or delivery mechanism. Price differences are not a "significant" difference to justify compounding.

~~f~~g. Preparation or Product: A compounded drug dosage form, a compounded dietary supplement, or a finished device.

~~g~~h. Quality Assurance (QA): Set of activities used to ensure that the processes used in the preparation of non-sterile or sterile drug products lead to products that meet predetermined standards of quality.

~~h~~i. **Quality Control (QC): Set of testing activities used to determine that the ingredients, components and final non-sterile or sterile drug products prepared meet pre-determined requirements with respect to strength, identity, quality, and purity.**

~~i~~j. **Repackaging: The subdivision or transfer of a product from one container or device to a different container or device. Repackaging does not constitute compounding, whether or not the product being repackaged was previously compounded.**

~~j~~k. **SOPS: Standard operating procedures.**

~~k~~l. **Stability: Extent to which a preparation retains, within specified limits, and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.**

~~l~~m. **USP/NF: The current edition of the United States Pharmacopeia/National Formulary.**

~~m~~n. **Validation: Documented evidence providing a high degree of assurance that specific processes will consistently produce a product meeting predetermined specifications and quality attributes.**

~~n~~o. **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.**

21.20.20 Definitions of Sterile Compounded Products by Risk Level.

a. Immediate Use CSPS:

(1) Immediate use CSPS are intended only for emergency or immediate patient administration of a CSP, and are exempt from the requirements for low-risk CSPS if:

(a) The compounding process involves a transfer of not more than three (3) commercially manufactured sterile nonhazardous products from the manufacturers' original containers and not more than two (2) entries into any one (1) container;

(b) The compounding process takes less than one (1) hour;

(c) Aseptic technique is followed when compounding occurs outside of class 5 air quality;

(d) Product administration begins no later than one (1) hour after product preparation; and

(e) The product is labeled with a one (1) hour BUD.

b. Low Risk CSPs;

(1) All low risk CSPs shall be compounded with aseptic manipulations within ISO Class 5 or better air quality. All PECs (CAI, CACI, LAFW, and BSC) shall be certified as required and shall maintain ISO Class 5 air quality.

(~~1~~2) Low risk CSPs with greater than 12-hour BUD: Applies to compounding sterile products that exhibit characteristics (a) and (b) stated below. ~~All low risk CSPs shall be compounded with aseptic manipulations entirely within ISO Class 5 or better air quality.~~ The products shall be prepared with sterile equipment, sterile ingredients and solutions and sterile contact surfaces for the final product. Low risk includes the following:

(a) The compounding involves only transfer, measuring, and mixing manipulations using no more than three commercially manufactured sterile products and no more than two entries into any one container or package of sterile product to make the CSP; and

(b) Manipulations are limited to aseptically opening ampules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

(~~2~~3) Low risk CSPs with 12-hour or less BUD: The LAFW or BSC shall not be located within an ISO Class 7 area. Applies to low-risk, nonhazardous or radiopharmaceutical CSPs dispensed pursuant to a patient-specific order which are prepared and administered within 12 hours of the preparation or

as stated in the corresponding manufacturer's package insert (whichever is less) and the following conditions are met:

~~(a) The PEC is a CAI; or~~

~~(b) The CACI cannot provide isolation from the room and maintain an ISO Class 5 environment during dynamic operating conditions; or~~

~~(c) The LAFW or a BSC cannot be located within an ISO Class 7 buffer area; and~~

~~(d) This shall not apply to chemotherapeutic preparations subject to USP/NF Chapter 800. Low risk CSPs with 12-hour or less BUD shall meet all of the characteristics of (e) through (h) below:~~

~~(e) PECs (LAFWs, BSCs, CAIs, CACIs) shall be certified as required and shall maintain ISO Class 5 air quality;~~

(~~f~~a) PECs shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination;

(~~g~~b) The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation or any area that could cause contamination. The segregated area shall not be located next to a sink; and

(~~h~~c) The specifications in cleaning and disinfecting the sterile compounding area, personnel training and competency evaluation of garbing, aseptic work practices and cleaning/disinfection procedures, and viable and non-viable environmental sampling testing shall be followed.

(d) This shall not apply to chemotherapeutic preparations subject to USP/NF Chapter 800.

c. Medium Risk CSPs: Sterile products exhibit characteristics (1), (2), or (3) stated below. When CSPs are compounded aseptically under low risk conditions, and one or more of the following conditions exists, such CSPs are at a medium risk level of contamination:

(1) Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions; or

(2) The compounding process includes complex aseptic manipulations other than the single volume transfer; or

(3) The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

d. High Risk CSPs: CSPs compounded under any of the following conditions are either contaminated or at high risk to become contaminated with infectious microorganisms:

(1) Products compounded from non-sterile ingredients or compounded with non-sterile components, containers or equipment before terminal sterilization; or

(2) Sterile contents of commercially manufactured products, CSPs that lack effective antimicrobial preservatives, and sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs are exposed to air quality worse than ISO Class 5 for more than 1 hour; or

(3) Before sterilization, non-sterile procedures such as weighing and mixing are conducted in air quality worse than ISO Class 7, compounding personnel are improperly garbed and gloved; or water–containing preparations are stored for more than 6 hours; or

(4) It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients.

21.30.00 Hazardous Drugs – Handling in Outlets.

21.30.10 Definitions. In addition to the definitions set forth above in Board Rules 21.00.30, 21.20.10, and 21.20.20, the following words and terms shall have the following meanings, unless the context clearly indicates otherwise.

a. Hazardous Drug: Any drug identified and publically listed as hazardous or potentially hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of the following six (6) criteria:

(1) Carcinogenicity;

(2) Teratogenicity or developmental toxicity;

(3) Reproductive toxicity in humans;

(4) Organ toxicity at low doses in humans and animals;

(5) Genotoxicity; and

(6) New drugs that mimic existing hazardous drugs in structure or toxicity.

21.30.20 All Board-registered outlets in this state that handle hazardous drugs shall comply with the most current provisions of USP/NF Chapter 800 < Hazardous Drugs – Handling in Healthcare Settings > by no later than the chapter's enforcement date as publically specified by the United States Pharmacopoeial Convention.

27.00.00 HOSPITAL SATELLITE PHARMACY.

27.00.10 Definitions.

a. "Hospital ~~S~~satellite ~~P~~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 ~~P~~pharmacy is located, has a different address than the ~~P~~primary ~~P~~pharmacy, and is housed in a building with a main entrance that is no more than one (1) mile from the main entrance to the building which houses the ~~P~~primary ~~P~~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 ~~P~~primary ~~P~~pharmacy is located.

b. "Primary ~~P~~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 ~~hospital satellite pharmacies~~ HSPs.

b. The ~~P~~primary ~~P~~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. ~~Hospital Satellite Pharmacies~~ 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.

~~d~~e. The compounding/dispensing area of an ~~Hospital Satellite Pharmacy~~ 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.

~~e~~f. Any room~~(s)~~ included within or adjacent to the compounding/dispensing area that ~~are~~ is separated from the compounding/dispensing area by a door must meet the following:

1. The ~~Hospital Satellite Pharmacy~~ HSP shall submit documentation required by the Board to remodel the compounding/dispensing area prior to the utilizing the room~~(s)~~ 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.

~~f~~h. All HSPs and all satellites ~~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.

~~g~~i. If the ~~Hospital Satellite Pharmacy~~ HSP engages in compounding/dispensing, there shall be a minimum of 12 continuous square feet of compounding/dispensing area, and a minimum of 6 continuous square feet of compounding/dispensing area for each person engaged in compounding/dispensing. 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.

~~h~~j. The free floor space behind any compounding/dispensing counters or work surfaces shall be not less than 30 inches in width;

~~i~~k. ~~If the Hospital Satellite Pharmacy engages in compounding/dispensing, the~~ The free floor space between rows of shelving shall be not less than 24 inches;

~~j~~l. If the ~~Hospital Satellite Pharmacy~~ HSP engages in compounding/dispensing, there shall be sufficient shelf, drawer and/or cabinet space for proper storage of prescription drugs and devices.

~~k~~m. If the ~~Hospital Satellite Pharmacy~~ 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.

~~l~~n. Any other professional and technical equipment appropriate and adequate for the type of practices the ~~Hospital Satellite Pharmacy~~ HSP engages in shall at all times be located within the compounding/dispensing area.

~~m~~o. If refrigerated drugs are stored at the ~~Hospital Satellite Pharmacy~~ 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 ~~either manually or~~ 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 ~~Hospital Satellite Pharmacy~~ 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.

~~n~~p. If frozen drugs are stored at the ~~Hospital Satellite Pharmacy~~ 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 ~~either manually or~~ 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 ~~Hospital Satellite Pharmacy~~ 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.

~~o~~q. There shall be a professional reference library available in the ~~Hospital Satellite Pharmacy~~ 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. CRS Title 12, Article 42.5; the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act.

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

3. Board 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 ~~P~~primary ~~P~~pharmacy may deem necessary.

27.00.30 Requirements for operation of an ~~Hospital Satellite Pharmacy~~ HSP

a. The pharmacist manager of the ~~P~~primary ~~P~~pharmacy shall have responsibility for the operation and control of the ~~Hospital Satellite Pharmacy~~ HSP;

b. For the purpose of recordkeeping, drug stocks of the ~~Hospital Satellite Pharmacy~~ HSP shall be included in the inventory of the ~~P~~primary ~~P~~pharmacy;

c. All records from the ~~Hospital Satellite Pharmacy~~ HSP shall be maintained at the ~~P~~primary ~~P~~pharmacy in accordance with Rule 11.00.00;

d. Pharmacist staffing at the ~~Hospital Satellite Pharmacy~~ HSP cannot be considered in the computation of the pharmacists to pharmacy technician ratio in the ~~P~~primary ~~P~~pharmacy;

e. Pharmacist staffing at the ~~P~~primary ~~P~~pharmacy cannot be considered in the computation of the pharmacists to pharmacy technician ratio in the ~~Hospital Satellite Pharmacy~~ HSP;

f. The ~~P~~primary ~~P~~pharmacy may distribute drugs to the ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ HSP shall display in the ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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.

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

27.00.50 Security. All ~~In every Hospital Satellite Pharmacy~~HSPs and additional satellites~~, all compounding/dispensing areas~~ shall comply with this rule.

a. When any compounding/dispensing area of an ~~Hospital Satellite Pharmacy~~ HSP is occupied by any employee, a pharmacist must be physically present within the same building of the ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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;

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 ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ HSP is located are as follows:**

1. **In an emergency situation and when a pharmacist is not in the building where the ~~Hospital Satellite Pharmacy~~ 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 ~~Hospital Satellite Pharmacy~~ HSP, the ~~P~~primary ~~P~~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 ~~Hospital Satellite Pharmacy~~ HSP r~~R~~egistration. If a registration of an ~~Hospital Satellite Pharmacy~~ HSP has expired, the ~~P~~primary ~~P~~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 ~~Hospital Satellite Pharmacy~~ HSP. Closure shall also be deemed to have occurred if the compounding/dispensing area is not open for business the minimum hours specified in 27.00.40.**

b. **Upon the closure of the ~~Hospital Satellite Pharmacy~~ HSP, it shall be the responsibility of the pharmacist manager of the ~~P~~primary ~~P~~pharmacy to relocate the chart orders**

and drugs to the ~~P~~primary ~~P~~pharmacy. Such relocation of records shall be made within 72 hours after closure of the~~ Hospital Satellite Pharmacy~~ HSP. The pharmacist manager shall notify the Board on a form provided by the Board, detailing the closure of the~~ Hospital Satellite Pharmacy~~ HSP within 72 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 (3) members, each appointed by the state veterinarian, which reviews matters concerning veterinary pharmaceuticals, as specified by this Board 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 42.5 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.