**DEPARTMENT OF REGULATORY AGENCIES**

**State Board of Pharmacy**

**STATE BOARD OF PHARMACY RULES AND REGULATIONS**

**3 CCR 719-1**

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

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**3.00.00 DISPENSING.**

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

3.00.20 Medical Need.

(a) No licensee or registrant shall compound, dispense, deliver or distribute any drug to any person in such quantity or in any situation where the licensee or registrant knows or reasonably should know said drug has no recognized medical utility or application. Violation of this Rule shall constitute prima facie proof of violation of section 12-280-126, C.R.S.

(b) One additional bottle of a prescription eye drop may be dispensed to a patient if the following conditions are met:

1. The corresponding patient's health benefit plan provides coverage for the prescription eye drops;

2. The additional bottle is requested by the insured or the health care provider at the time the original prescription is dispensed;

3. The original order states that one additional bottle is needed by the insured for use in a day care center, school, or adult day program;

4. The additional bottle is limited to one additional bottle every three months; and

5. The total number of bottles dispensed does not exceed the total number of bottles prescribed as stated on the original order when accounting for authorized refills assigned to the original order by the prescriber, if applicable.

(c) A prescription eye drop may be refilled if the following conditions are met:

1. The refill is requested by the insured at least twenty-one days for a thirty day supply of eye drops, forty-two days for a sixty day supply of eye drops, or sixtythree days for a ninety day supply of eye drops, from the later of the date that the original prescription was dispensed to the insured or the date that the last refill of the prescription was dispensed to the insured; and

2. The original prescription order states that additional quantities of prescription eye drops are needed and the refill requested by the insured does not exceed the number of additional quantities needed.

(d) The pharmacist may not dispense a prescription drug or a controlled substance to a practitioner based on an order that does not list a specific patient. A prescription order for "office use" is not a valid order. Compounded prescription drugs distributed to veterinarians for "office stock" as defined in section 12-280-121(5)(b), C.R.S., must comply with the requirements of Rules 11.00.00 and 21.00.00.

3.00.21 A pharmacist shall make every reasonable effort to ensure that any order, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized practitioner. A pharmacist shall not dispense a prescription drug if the pharmacist knows or should know that the order for such drug was issued without a valid preexisting patient practitioner relationship. Such relationship need not involve an in-person encounter between the patient and practitioner if otherwise permissible under Colorado law. A pharmacist may, in good faith, prescribe or dispense an opiate antagonist pursuant to an order that was issued without a valid preexisting patient-practitioner relationship that is approved by the Federal Food and Drug Administration for the treatment of a drug overdose.

3.00.22 The prescribing or dispensing of an opiate antagonist, as described in Rule 3.00.21, by a pharmacist shall not constitute unprofessional conduct pursuant to section 12-280-126, C.R.S., if he or she prescribed or dispensed the opiate antagonist in good faith pursuant to an order or standing orders and protocols issued to or for individuals or entities described in section 12-30-110, C.R.S.

a. Each prescription drug outlet shall maintain, in a uniform and readily retrievable manner for at least two years from the date of latest transaction related to a pharmacist initiated order or standing order, the following record detailing the dispensing of an opioid antagonist pursuant to a pharmacist initiated order or standing order:

1) The full name of the patient, person who is in a position to assist a person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event, first responder, unit of local government, or harm reduction organization receiving the drug;

2) The full address of the first responder, unit of local government, or harm reduction organization receiving the drug;

3) The name, strength and dosage form of the drug dispensed;

4) The quantity of drug dispensed; and

5) The date of dispensing.

3.00.23 Dispensing without an order.

a. A pharmacist may dispense an emergency supply of a chronic maintenance drug, as defined in section 12-280-103(9.5)(a) and (b), C.R.S., to a patient without a current, valid order under the conditions set forth in section 12-280-125.5, C.R.S. When an emergency dispensing occurs, the dispensing pharmacist, or his or her designee, shall immediately notify the practitioner of record related to the emergency dispensing, in writing, detailing the:

(1) Name, address, and telephone number of dispensing pharmacy;

(2) Name, strength, dosage form, directions, and quantity of drug dispensed;

(3) Name of patient and corresponding patient's date of birth; and

(4) Date of emergency dispensing.

b. Records related to the dispensing of an emergency supply of a chronic maintenance drug shall be detailed and maintained in the same manner as all other dispensing transactions in compliance with all applicable provisions of Board Rules 2.00.00, 3.00.00, 11.00.00, 21.00.00, and 26.00.00.

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

a. The receiving prescription drug outlet records on the prescription order the name and address of the originating prescription drug outlet and the date the order was received by the receiving prescription drug outlet;

b. The receiving prescription drug outlet maintains the order as a prescription order and complies with all requirements for prescription orders specified in Rules 2.01.10 through 2.01.40, 3.00.10 through 3.00.51, and 11.04.10; and

c. The originating prescription drug outlet records on the LTCF chart order the name and address of the receiving prescription drug outlet and the date the order was provided to the receiving prescription drug outlet.

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

a. The prescription is delivered directly from the originating outlet to the receiving outlet;

b. The prescription is at no time in the physical possession of the patient until after the prescription has been reconstituted;

c. The prescription is reconstituted according to the corresponding manufacturer’s directions;

d. The prescription is not a controlled substance;

e. The pharmacist at the receiving outlet does not alter the prescription or its original labeling in any way other than to reconstitute, re-label for re-dispensing for administration, and properly store the prescription; and

f. The originating outlet is ultimately accountable to the Board for the accurate dispensing of the original prescription, and the receiving outlet is ultimately accountable for the accurate reconstitution and re-dispensing of the prescription.

3.00.30 Labeling.

a. When a prescription drug is dispensed pursuant to an order, the name of the drug that appears on the container label shall correspond with the identity of the drug contained therein unless otherwise requested by the practitioner.

b. When a prescription drug is dispensed to a patient for outpatient use and contains an opioid that is not prescribed for the treatment of a substance use disorder or is a partial opioid

antagonist, the label or container shall bear a notification that states, or is substantially equivalent to: “Caution: Opioids carry a risk of overdose and addiction.”

c. In addition to complying with all applicable accessibility labeling requirements, including but not limited to requirements relating to visual impairment, pursuant to section 12-280- 124, C.R.S., each prescription drug outlet shall apply to the Board, for its approval, if the prescription drug outlet offers a patient an alternative method to access a prescription drug label other than the methods specified in section 12-280-124(4)(b)(I) to (4)(b)(IV), C.R.S. When applying to the Board for an alternative method, each prescription drug outlet shall demonstrate to the Board that the method to access a prescription drug label is substantially similar to the method of access the patient requested and meets the needs of the patient.

3.00.40 Expiration Dating. No drug or device shall be dispensed which will be outdated prior to utilization by the consumer, based on the practitioner's directions for use. 3.00.50 Initial Interpretation and Final Evaluation.

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

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

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

1) Known allergies;

2) Rational therapy and contraindications;

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

4) Reasonable directions for use;

5) Potential or actual adverse drug reactions;

6) Drug-drug interactions;

7) Drug-food interactions;

8) Drug-disease contraindications;

9) Therapeutic duplication;

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

11) Abuse/misuse.

d. A pharmacist shall conduct an initial interpretation of each new order and a pharmacist shall conduct the final evaluation of each order dispensed. When refills are dispensed, the pharmacist making the final evaluation shall be held accountable for the appropriate dispensing of refills. The pharmacist manager shall be held accountable for the maintenance of all appropriate records.

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

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

3.00.51 Records of Initial Interpretation and Final Evaluation.

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

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

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

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

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

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

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

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

4) Such written notice shall be signed and dated or electronically approved if version and approval histories are available by the pharmacist manager. In the event the pharmacist

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

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

6) The outlet shall post these notices on a wall directly next to the outlet's most current Board registration or electronically publish a secure version of the notice.

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

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

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

a. The patient, patient's caregiver, or practitioner who authorized the original prescription shall authorize the flavoring of each new and, if applicable, refilled prescription;

b. The flavor additive shall in no way compromise the stability, safety, or efficacy of the dispensed drug.

c. No expired flavor additive shall be incorporated into a prescription. No flavor additive shall be incorporated which will expire prior to utilization by the patient, based on the practitioner's directions for use.

d. For flavoring additives that do not have expiration dates assigned by the manufacturer or supplier, a pharmacist shall clearly and legibly label the container with the date of receipt and assign a conservative expiration date, not to exceed three years after receipt, to the flavoring additive. In no event shall the labeled date of receipt or assigned expiration date be later altered after originally labeling the container.

e. The following information shall be recorded and maintained in a suitable hard-copy or electronic dispensing record for a period of two years from the date of flavoring the corresponding new or refilled prescription. This record shall be made available, in printed form, for the Board or its representatives immediately upon the request of the Board or its representatives.

1) Additive's flavor;

2) Flavor additive's manufacturer

3) Flavor additive's lot number (if available); and

4) Flavor additive's expiration date.

f. The pharmacist responsible for conducting the final evaluation of a new or refilled prescription shall also be responsible for the flavoring of the prescription as specified in subsections a., b., and c. of this Rule 3.00.55.

g. The pharmacist manager shall be responsible for subsection d. of this Rule 3.00.55 and the maintenance of records as specified in subsection e. of this Rule 3.00.55.

3.00.60 When a substitution is made on a prescription order, a patient shall be given oral and written notice of this fact at the time such substitution initially occurs, except as provided in section 12-280-125, C.R.S. On subsequent refilling of a prescription order, such oral and written notices shall not be required unless, in the professional judgment of the pharmacist, the best interest of the patient will be served by giving such notices.

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

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

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

3.00.81 Definitions.

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

a. "Automated cassette" is a container that is filled with a drug. This container may count the drug and may package the drug into a container suitable for dispensing, and may affix a label to the container. These cassettes may be used to dispense drugs in a traditional dispensing system or may be used to package unit-dose medication, or drugs in a unit of issue packaging system.

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

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

d. "Licensed Facility" means any of the following facilities licensed by the Colorado Department of Public Health and Environment: community mental health center, acute treatment unit, hospital unit, inpatient hospice, nursing care facility, assisted living residence, or long-term care facility.

e. "Medical Device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required to be labeled pursuant to 21 CFR Part 801.

f. "Medical Supply" means a consumable supply item that is disposable and not intended for reuse.

g. "Nonprofit Entity" means a Board registered prescription drug outlet or other outlet which has nonprofit status, or an out-of-state entity with legal authority to both possess a prescription drug and receive a donated prescription drug distributed from a Board registered outlet in the state of Colorado.

h. "Originating Prescription Drug Outlet" means the prescription drug outlet which initially dispensed the prescription for a resident of a facility.

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

j. "Single dose package" means a package which contains a quantity of a drug intended for administration as a single dose.

k. "Traditional dispensing system" means a drug package system in which individual doses are not packaged in unit dose packages or unit of issue packages.

l. "Unique identifier" means an implicit or explicit unique identifier from which the originating prescription number can be determined.

m. "Unit dose dispensing system" means a drug distribution system which is in a prescription drug outlet or hospital other outlet and uses unit dose packages or unit of issue packages that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

n. "Unit dose package" means a package which contains one pharmaceutical unit.

o. "Unit of issue package" means a package which provides multiple units of doses but separated in a medication card or other specifically designed container.

3.00.82 General Provisions

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

1) A prescription drug outlet that complies with Rules 3.00.82 through 3.00.89 may accept prescriptions, medical devices, and medical supplies for return, dispensing, and donation.

2) A hospital prescription drug outlet may accept prescriptions and drugs for dispensing or reissue from all areas of the hospital, provided that the integrity of the product and package are maintained and the following requirements are met:

(a) An appropriate, uniformly maintained and readily retrievable record shall be maintained which indicates at least the total number of doses of the drug which were actually administered. This record may be combined with the record permitted by Rule 2.01.20(c); or

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

(I) The name of the drug;

(II) The strength of the drug;

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

(IV) The quantity of the drug;

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

(VI) The date of the return.

b. No prescription drug returned for redispensing or donation from a facility or donated by a prescription drug outlet shall be redispensed if it expires prior to utilization by the consumer based on the prescribing practitioner's directions for use.

c. Rules 3.00.80 through 3.00.89 do not apply to the Colorado Cancer Drug Repository.

3.00.83 Entities Eligible to Donate or Return Prescriptions.

The following may donate or return drugs:

a. A correctional facility as defined in Rule 3.00.81(b), a licensed facility as defined in Rule 3.00.81(d), or any other facility that is required to be licensed pursuant to section 25-3- 101, C.R.S., may return prescriptions to a prescription drug outlet.

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

c. A prescription drug outlet may donate a returned or donated prescription to a nonprofit entity as defined in Rule 3.00.81(g) or to a practitioner authorized by law to dispense the prescription.

3.00.84 Eligibility for Return or Donation.

a. For all prescriptions, medical devices, or medical supplies accepted for return or donation, the prescription drug outlet must ensure that the prescription, medical device, or medical supply was properly stored prior to return or donation. This includes storage at the facility, and shipment to and from the facility.

b. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are eligible for return or donation are as follows:

1) Drugs which are liquid and the vial is still sealed and properly stored;

2) Drugs that have been individually packaged and the packaging has not been damaged; and

3) Drugs that are in the original, unopened, sealed, and tamper-evident unit dose package, unit of issue package, or unit dose dispensing system.

c. Drugs which have been dispensed to a resident of a correctional facility, licensed facility, or any other facility that is required to be licensed pursuant to section 25-3-101, C.R.S., that are not eligible for Return or Donation are as follows:

1) Any drug declared to be a controlled substance under any state or federal law or rule except as provided in Rule 3.00.82(a)(2);

2) Any drug dispensed in a traditional dispensing system;

3) Any drugs dispensed in a customized patient medication package;

4) Any drug packaged in a single dose package, a unit dose dispensing system, a unit dose package, or a unit of issue package that is not labeled in accordance with Rules 3.01.20 and 3.01.21;

5) A compounded drug;

6) Drugs that are adulterated or misbranded as determined by the pharmacist;

7) Drugs that require refrigeration, freezing, or special storage;

8) Drugs that require special registration with the manufacturer;

9) Drugs that will expire prior to utilization by the consumer, based on the prescribing practitioner's directions for use;

10) Dispensed drugs that are received from facilities or pharmacies located outside of Colorado; and

11) Any drug that was not dispensed pursuant to an order.

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

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

1) Name and address of facility or donating prescription drug outlet;

2) Name and address of originating prescription drug outlet;

3) Prescription number or unique identifier assigned at originating prescription drug outlet;

4) Name and address of each prescription drug outlet having possession of the drug, device, or supply after the originating prescription drug outlet and the dates the product was in each prescription drug outlet's possession.

5) Date of return or donation;

6) Name, strength, and NDC number of drug received;

7) Name of medical device or medical supply received; if applicable;

8) Quantity received;

9) Date received;

10) Drug, medical device, or medical supply expiration date;

11) Receipt record must state, "Returned or Donated Prescription, Device, or "Supply"

b. Records detailing the receipt of returned or donated prescriptions, devices, and supplies, as required by Rule 3.00.84(a)(1) through (11) may be maintained electronically if the following requirements are met:

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

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

3) Have a "lock-out" feature that prevents editing of receipt information;

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

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

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

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

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

a. Returned or donated prescriptions, medical devices, and medical supplies shall be stored in a separate area from other drug stocks belonging to the pharmacy. This area shall be conspicuously labeled with a sign indicating that such area contains only returned or donated prescriptions, medical devices, or medical supplies.

b. An entity that receives a donated medication, medical device or medical supply may charge the end user a handling fee, which shall not exceed three dollars for each complete prescription, medical device or medical supply dispensed to the end user and shall not resell the donated medication, medical device or medical supply for profit.

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

a. Special Conditions for Dispensing Returned or Donated Drugs:

1) Drug products in manufacturer's unit dose or unit of issue packages may be redispensed as often as necessary, provided that the integrity of the product and package are maintained.

2) Drug products which have been packaged into unit dose or unit of issue packages in the prescription drug outlet may be redispensed one time only, except as provided for in Rule 3.00.82((a)(2), provided that the integrity of the product and the package are maintained.

3) Drug products which have been packaged into unit of issue packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (5) below. Partiallyused unit of issue packages may not be emptied and the drugs removed and packaged, nor may additional units of medication be added to partially-used unit of issue packages.

4) Drug products which have been packaged into single dose packages in the prescription drug outlet may be redispensed one time only and then only in the package in which originally dispensed, except as provided in (5) below. Single dose packages may not be emptied and the drugs removed and packaged.

5) Drug products which have been packaged into unit of issue packages or single dose packages may be removed from such packages and packaged for dispensing in a traditional dispensing system.

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

b. Records of Dispensing

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

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

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

1) Nonprofit entity as defined in Rule 3.00.81(g); or

2) A practitioner authorized by law to dispense the drug.

b. Records of donation shall include the following:

1) The name of the drug, medical device, or medical supply;

2) The strength of the drug;

3) The dosage form if appropriate;

4) The quantity of the drug, medical device, or medical supply;

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

6) The date of donation;

7) The name and address of the donating prescription drug outlet;

8) The name and address and registration number of the nonprofit entity receiving the drug, medical device, or medical supply, or the name, address, and license number of the practitioner receiving the drug, medical device, or medical supply.

9) The name and address of the originating prescription drug outlet;

10) The prescription number or unique identifier assigned to the prescription at the originating prescription drug outlet.

11) The date the medication expires; and

12) The name and address of each prescription drug outlet, other than the originating prescription drug outlet, having possession of the prescription and the dates the prescription was in that prescription drug outlet's possession.

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

d. Records detailing the donation of prescriptions, medical devices, and medical supplies, as required by Rules 3.00.88(b)(1) through (12) may be maintained electronically if the following requirements are met:

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

2) Have and maintain a complete on-line donation file that is printable on the inspector's request;

3) Have a "lock-out" feature that prevents editing of donation information;

4) The Board or its inspectors must be able to inspect and review all of the donation transactions of the outlet for the preceding two years. Therefore, immediately upon the oral or written request of the Board or its inspectors, the outlet shall either:

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

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

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

3.00.89 Record Retention a. All records of receipt and dispensing shall be maintained for a period of two years from the date of receipt, or from the last dispensing transaction date. Such records shall be

maintained separately from all other records of the prescription drug outlet. b. All records of donation shall be maintained for a period of three years from the date of donation. Such records shall be maintained separately from all other records of the prescription drug outlet.

3.00.90 Prescriptions Dispensed but Not Delivered. When a drug has been dispensed pursuant to a prescription or LTCF chart order but has not been delivered to the ultimate consumer, the drug may be returned to stock for subsequent redispensing provided that:

a. It is stored in the container in which it was dispensed, and maintains a label that accurately identifies its contents with respect to the original prescription label.

(1) A prescription label may be removed if the container is in the manufacturer's original sealed packaging and the removal of the label does not cause an unreadable expiration date and lot number on the manufacturer's packaging.

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

(1) Prescription number;

(2) Drug name and strength;

(3) Quantity returned to stock;

(4) Date of return; and

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

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

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

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

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

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

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

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

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

a. The prescription drug outlet complies with Rules 3.00.90(a), (b), and (c);

b. The storage conditions during the transport of the prescription to and from the other outlet do not in any way compromise the integrity or stability of the drug;

c. No controlled substance prescriptions may be returned to stock; and

d. No compounded or flavored prescription may be returned to stock.

3.00.92 A prescription drug that has been dispensed by an automated cassette device may be returned to a pharmacy cassette or any automated dispensing device receptacle for redispensing as long as the integrity of the medication has not been altered, bar code scanning technology is used for returning the drug, qualifications for returning the drug are maintained, and the expiration date of the drug has not passed. A pharmacy technician may carry out the process of prepackaging the drug into an automated cassette.

3.01.00 Packaging.

3.01.10

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

b. Such packaged drugs shall only be dispensed or distributed from the premises where packaged. Such packaged drugs shall only be distributed as provided in Rule 3.01.10(d).

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

d. The following prescription drug outlets may distribute packaged medications without limitation to prescription drug outlets and other outlets under common ownership:

1. Prescription drug outlets owned and operated by a hospital that is accredited by the joint commission on accreditation of healthcare organizations or a successor organization pursuant to 12-280-120(15)(b), C.R.S;

2. Prescription drug outlets operated by a health maintenance organization as defined in section 10-16-102, C.R.S.; and

3. The Colorado Department of Corrections.

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

a. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of (d), (e), (f), (g), and (h) of this Rule may be omitted from the labeling and maintained in such record. An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot packaged. In another outlet the record shall be signed by the

person specified in the Board approved protocol. The record shall be retained for two years from the date of packaging unless otherwise required by law or rule.

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

c. A suitable expiration date, which shall be not later than the expiration date on the manufacturer's container, or one year from the date the drug is packaged, whichever is less. Sterile packaged product beyond-use dating shall comply with Rule 3.01.34(h)(3));

d. The identity of the manufacturer or distributor;

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

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

g. The date the product was packaged;

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

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

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

3.01.22 Filling of automated cassettes.

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

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

1. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of 4, 5, 6, 7, and 8 of this Rule may be omitted from the labeling and maintained in such record. The record shall be retained for two years from the date of packaging, unless otherwise required by law or rule.

2. Name and strength of the medication;

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

4. The identity of the manufacturer or distributor;

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

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

7. The date the product was packaged;

8. The identity of the individual responsible for packaging, or in the case as provided in this Rule 3.01.22(f), the identity of the persons responsible for packaging;

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

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

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

f. A pharmacy technician or pharmacy intern may replenish automated cassettes without the need for a pharmacist's verification as long as the pharmacy technician uses bar code technology that checks the accuracy of the medication or a second pharmacy technician performs the verification.

3.01.23 Maintenance of automated cassette records.

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

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

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

3.01.24 Electronic Maintenance of Packaging Records.

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

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

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

c. The prescription drug outlet must:

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

Or

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

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

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

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

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

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

1. Name and strength of the medication;

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

3. The identity of the manufacturer or distributor;

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

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

6. The date the product was packaged;

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

3.01.25 Maintenance and cleaning of automated cassettes

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

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

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

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

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

3.03.00 Customized Patient Medication Packages (Med Paks).

3.03.10 When a unit dose, single dose, unit of issue or customized patient medication package is dispensed pursuant to an order, the prescription shall comply with all requirements of section 12-280-124(2), C.R.S. Container requirements of a prescription for the purpose of unit dose systems may be broadened to include trays, bins, carts and locked cabinets or drawers. Additionally, a customized patient medication package shall comply with all the following requirements:

a. Labeling

The patient med pak shall bear a label stating

(1) The name of the patient;

(2) A serial number for each of the orders detailing the drug products contained therein;

(3) The name, strength, and total quantity of each drug product contained therein;

(4) The directions for use and cautionary statements, if any, contained in the prescription order for each drug product therein;

(5) Any storage instructions or cautionary statements;

(6) The name of the prescriber of each drug product therein;

(7) The date of preparation of the patient med pak, the expiration date shall not exceed 90 days from the date of preparation; and

(8) The name, address, and telephone number of the dispenser.

b. Record Keeping.

(1) Patient name and address;

(2) The serial number of the order for each drug in product contained therein;

(3) Descriptive information sufficient to allow subsequent preparation of an identical patient med pak;

(4) Date of preparation of the patient med pak and the expiration date assigned;

(5) Any special labeling instructions; and

(6) The identity of the pharmacist who prepared the patient med pak.

c. Packaging

(1) Each container shall meet or exceed United States Pharmacopoeia standards.

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

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

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

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

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

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

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

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

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

3.04.00 Colorado Cancer Drug Repository Program. [Repealed]

3.05.00 Pharmacist Prescribing and Dispensing Over-the-Counter Medications

3.05.10 Pharmacists, pursuant to 12-280-103(34), C.R.S., may prescribe and dispense certain over-thecounter medications (“OTC Medications”) to recipients under the Colorado Medical Assistance Act.

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

3.05.30 When prescribing such OTC medications, the pharmacist shall issue a prescription order as defined in 12-280-103(31)(a), C.R.S. The prescribing pharmacist’s name shall be used on the prescription order as the name of the practitioner.

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

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

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

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

3.05.80 When dispensing the medication, the pharmacist shall label the product with all labeling requirements of 12-280-124, C.R.S. The prescribing pharmacist's name shall be used on the label as the name of the practitioner.

3.05.90 Upon delivery of the medication to the recipient, the pharmacist shall provide consultation with the recipient or his or her caregiver as required by the Colorado Department of Health Care Policy and Financing. The Colorado Department of Health Care Policy and Financing sets forth the requirements in 10 CCR 2505-10, 8.800 of June 30, 2018. This incorporation does not include later revisions of the rule. Copies of the rule are available for public inspection during regular business hours at 1570 Grant Street, Denver, Colorado, 80203. The rules are readily available in written or electronic form at http://www.sos.state.co.us/CCR/GenerateRulePdf.do?ruleVersionId=7643&fileName=10%20CCR%202505-10%208.800. The rules are available for a reasonable fee from the Department of Regulatory Agencies, Division of Professions and Occupations.

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

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**19.00.00 ADMINISTRATION.**

19.01.00 Vaccines and Immunizations.

19.01.10 Qualifications.

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

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

b. Pharmacy interns, as directly part of their normal schedule or college of pharmacy curriculum, who are trained to administer vaccines and immunizations under this Board Rule 19.01.10(c) may administer vaccines and immunizations under the direct supervision of another regulated individual as defined by Board Rule 4.00.10(l) authorized by law to administer vaccines and immunizations as part of their scope of practice.

c. Licensees shall be considered "trained" to administer vaccines and immunizations to a person only if:

(1) The pharmacist or pharmacy intern has completed a pharmacy-based immunization delivery course of at least twenty hours of training, including didactic and live hands-on training that is either accredited by the Accreditation Council for Pharmacy Education or provided by an ACPE accredited school or college of pharmacy as part of obtaining a pharmacy degree.

(2) The pharmacy technician has completed a pharmacy based immunization administration course of at least four hours of training including didactic and live hands-on training that is accredited by the Accreditation Counsel for Pharmacy Education. Proof of completion of this training shall be posted at the pharmacist's, pharmacy intern's, or pharmacy technician's main practice location(s).

(3) The pharmacist, pharmacy intern, or pharmacy technician holds a current basic cardiopulmonary resuscitation (CPR) certification issued by the American Heart Association or the American Red Cross or a basic cardiac life support certification. If the CPR certification has no expiration date, current means the certification must have been issued within the last two years. Proof of certification shall be available at licensee's main practice location.

(4) The vaccines are administered in accordance with CDC guidelines. The CDC guidelines pertaining to vaccine administration, incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guidelines shall be provided at cost upon request. The Program Director or the Program Director's designee will provide information regarding how the incorporated guideline may be examined at any state public depository library. The guideline is also available from the organization originally issuing the guideline as follows: Centers for Disease Control and Prevention (https://www.cdc.gov/vaccines/hcp/admin/admin-protocols.html (reviewed May 16, 2018)). This rule does not include any later amendments or editions of the guideline.

d. The prescription drug outlet shall have a current version available, either in hard copy or electronically available, of the CDC reference "Epidemiology and Prevention of VaccinePreventable Diseases". The CDC guideline referencing "Epidemiology and Prevention of Vaccine-Preventable Diseases," incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guideline or reference shall be provided at cost upon request. The Program Director or the Program Director's designee will provide information regarding how the incorporated guideline or reference may be examined at any state public depository library. This guideline or reference is also available on the Centers for Disease Control and Prevention's website: https://www.cdc.gov/vaccines/pubs/pinkbook/ (13th Edition (2015). This rule does not include any later amendments or editions of the guideline or reference.

19.01.20 A trained pharmacist may delegate the administration of vaccines and immunizations only to a trained pharmacy intern or pharmacy technician.

19.01.30 Policies and Procedures

a. Prior to administering vaccines or immunizations, pharmacists, pharmacy interns, and pharmacy technicians must be trained in a pharmacy-based immunization course accredited as detailed in Rule 19.01.10(c).

b. The prescription drug outlet must maintain and follow written policies and procedures for handling and disposal of used and contaminated equipment and supplies. The prescription drug outlet must obtain a physician protocol for addressing allergic reactions to immunizations.

c. The prescription drug outlet must give the appropriate "Vaccine Information Statement" (VIS) to the patient or legal representative with each dose of vaccine covered by these forms. The pharmacist must ensure that the patient or legal representative has received and signed the informed consent form and has had their questions answered prior to the administration of the vaccine.

d. The prescription drug outlet must report adverse events as required by the Vaccine Adverse Events Reporting System (VAERS) and to the primary care provider as identified by the patient.

19.01.40 Recordkeeping.

a. The following information must be maintained by the prescription drug outlet for three years for each dose of vaccine or immunization administered:

(1) The name, address, and date of birth of the patient;

(2) Patient responses to screening questions for indications/contraindications to the immunization or vaccine being administered;

(3) The date of the administration and site of injection of the immunization or vaccine;

(4) The name, dose, manufacturer, lot number, and expiration date of the vaccine or immunization;

(5) The name or identifiable initials of the administering pharmacist. If the administration is by a pharmacy intern or pharmacy technician, the initials of both the intern or pharmacy technician and supervising pharmacist;

(6) The signed informed consent document for each administration;

(7) Which vaccine information statement (VIS) was provided;

(8) The date the VIS was provided; and

(9) The name and address of the facility at which the vaccine or immunization was administered, if administered off-site.

b. The above records shall be maintained separately from other records of the prescription drug outlet.

c. All records required to be maintained pursuant to this Rule 19.00.00 may be maintained electronically so long as such records are maintained in a uniform and readily retrievable manner, are printable upon request of the Board or its inspectors, and can be reviewed at a viewable rate that may customarily be reviewed when otherwise in hard-copy form.

19.01.50 Off-Site Administration of Immunizations and Vaccines

a. A prescription drug outlet may allow a licensed pharmacist to remove immunizations and vaccines from the prescription drug outlet, provided the following requirements are met:

(1) The prescription drug outlet maintains records which detail the removal of the immunizations and vaccines with at least the following information:

(a) Name, strength, dosage form, and NDC number of the immunization or vaccine removed;

(b) Quantity removed;

(c) Date removed;

(d) Name and license number of pharmacist removing the immunization or vaccine.

(2) The immunizations and vaccines are properly stored at compendial temperatures during transport and storage at the off-site location.

(3) The vaccines and immunizations shall be secured during transport and storage at the off-site location so as to allow only licensed pharmacists, pharmacy interns, and pharmacy technicians affiliated with the prescription drug outlet to have access to them.

(4) The remaining vaccines and immunizations shall be returned to the prescription drug outlet the day they were removed.

(5) The prescription drug outlet shall maintain records detailing the vaccines and immunizations returned with at least the following information:

(a) Name, strength, dosage form, and NDC number of the immunizations or vaccines returned;

(b) Quantity returned;

(c) Date returned; and

(d) Name and license number of pharmacist returning the immunization or vaccine.

b. All required records shall be maintained in a manner that is uniformly maintained, readily retrievable, and available for inspection for a period of three years from the date of removal off immunizations or vaccines for off-site administration.

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**Appendix G**

**Colorado State Board of Pharmacy Statewide Protocol**

**Medications for Opioid Use Disorder**

Per authority of CRS 12-280-604, this collaborative pharmacy practice statewide protocol authorizes qualified, Colorado-licensed, pharmacists (“Pharmacists”) to provide pertinent assessment of patients with opioid use disorder (OUD) and prescribe FDA-approved products indicated for OUD for the purpose of medication assisted treatment (MAT) for the treatment of OUD, in collaboration with other healthcare

practitioners, and in accordance and compliance with standards of care and all applicable state and federal laws and rules.

Pharmacists may prescribe and dispense FDA-approved product(s) indicated for OUD to eligible patients according to indications and contraindications recommended in current guidelines from the American Society of Addiction Medicine (ASAM) and the Substance Abuse and Mental Health Services Administration (SAMHSA).

The ASAM guidelines and the SAMHSA guidelines, incorporated by reference, may be examined at the State Board of Pharmacy, 1560 Broadway, Suite 1350, Denver, Colorado 80202, and are available for public inspection during normal business hours, Monday through Friday, except when such days are state holidays. Certified copies of the incorporated guidelines may be requested from the State Board of Pharmacy. A charge for certification or copies may apply. The guidelines are also available from the organizations originally issuing the guidelines as follows:

• The ASAM National Practice Guideline for the Treatment of Opioid Use Disorder – 2020 Focused Update. Default. Published 2020. https://www.asam.org/quality-care/clinicalguidelines/national-practice-guideline.

• SAMHSA. Medications, counseling, and related conditions. www.samhsa.gov Published 2023. https://www.samhsa.gov/medications-substance-use-disorders/medicationscounseling-related-conditions.

This rule does not include any later amendments or editions to the codes, standards, guidelines, or rules incorporated herein.

Prior to prescribing Medications for Opioid Use Disorder (MOUD) per this protocol, the pharmacist must:

1. Identify a collaborating practitioner (collaborating primary care practitioner or other practitioner) or a collaborating entity that agrees to this protocol-based care.

2. Hold a current Drug Enforcement Agency (DEA) registration for Schedule III-V Controlled Substances.

3. Hold a current license to practice pharmacy in Colorado.

4. Be engaged in the practice of pharmacy.

5. Have earned a Doctor of Pharmacy degree or completed at least 5 years of experience as a licensed pharmacist.

6. Carry adequate professional liability insurance as determined by the Board.

7. Complete a training program accredited by the Accreditation Council for Pharmacy Education, or its successor entity, pursuant to the protocol (in compliance with Board Rule 17.00.50 b.2.).

8. Pharmacists must also follow all board rules for statewide protocols in section 17.00.00 herein.

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

**Records:**

A. Pursuant to Pharmacy Board Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's collaborating practitioner and/or document changes to the patient's medical record. If the patient does not have a primary care practitioner or is unable to provide contact information for his or her primary care practitioner, the pharmacist shall provide the patient with a written record of the drugs or devices furnished, and laboratory test(s) ordered, and any test results.

B. Pharmacists shall comply with all aspects of Pharmacy Board Rules 17.01.00 and 17.02.00 with respect to the maintenance of proper records.

**Medications for Opioid Use Disorder (MOUD) Protocol**

Under this protocol, pharmacists may assess patients with OUD and determine the necessity of MOUD. Traditionally, medication assisted treatment (MAT) means a combination of medications and behavioral therapy, such as buprenorphine and all other medications and therapies approved by the Federal Food and Drug Administration, to treat opioid use disorder. MOUD means treatment for an opioid use disorder using medications approved by the FDA for that purpose and prescribed, dispensed or administered in accordance with national, evidence-based published guidance. Using this protocol, qualified pharmacists may prescribe, dispense and administer MOUD listed in Table 1, or any other Schedule III, IV, and V FDA-approved/ASAM recommended medications or regimens as they become available.

Eligibility Requirements:

- The patient is at least 18 years of age.

- The practitioner has a diagnosis of moderate or severe opioid use disorder (OUD) according to DSM-5 criteria; or, the patient is in opioid withdrawal as assessed by a Clinical Opiate Withdrawal Scale (COWS) score ≥ 5, and in the absence of a diagnosis of moderate/severe OUD, the patient may be given an initial supply of 72 hours' worth of medication, pending a practitioner diagnosis to continue beyond that time frame.

- The patient has no known contraindications to MOUD agents.

**Screening and Consent Requirements:**

**Patient Notice and Consent**

- Each patient shall be provided with voluntary enrollment for protocol care and shall consent to participate in the protocol.

- Patients can be treated via the protocol via Practitioner Referral or Self-Referral.

o For patients who self-refer to the pharmacist for treatment, the pharmacist will have direct communication with a collaborating practitioner to review the treatment plan, by an established method and frequency.

**Screening Requirements**

- Screen for concurrent medical issues and history of/diagnosis of moderate or severe OUD.

- Medication records from pharmacy system and from the prescription drug monitoring program (PDMP), including past buprenorphine regimens for OUD.

- Patient history including (but not limited to):

- o Current COWS score.
- o Drug Allergies.
- o Medication list, include prescribed, non-prescribed, over the counter, and herbals, nonprescribed buprenorphine used for withdrawal.
- o Approximate last time opioids and any other drug (s) were used.
- o History of overdose.
- o Possession of naloxone, if not then offer naloxone via standing order.
- • Order labs in accordance with current ASAM or SAMHSA guidelines, or as agreed to with collaborating practitioner or entity. Therapy should not be withheld for pending labs (if indicated). Abnormal results received by the pharmacist will be shared and discussed with collaborating practitioner or entity as agreed upon.
- • Pharmacist will take and assess blood pressure.
- • Take into consideration results of or testing for pregnancy.

**Table 1: Medication Options***

| Drug | Mechanism | Indication | Contraindications | Notes |
|---|---|---|---|---|
| **Buprenorphine** | Partial Mu-Opioid Receptor Agonist | Opioid use disorder<br><br>Opioid withdrawal | • Hypersensitivity to buprenorphine<br><br>• Severe liver impairment | Patients currently using alcohol, sedatives or anxiolytics should be cautioned about increased CNS depression. |
| **Naltrexone** ((Extended Release ER) injection | Opioid antagonist | Prevention of return to use in patients who are not currently physically dependent on opioids. | • Current physical dependence on opioids, including partial agonists<br><br>• In acute opioid withdrawal<br><br>• Failure of a naloxone challenge<br><br>• Positive opioid test<br><br>• Hypersensitivity to naltrexone<br><br>• Previous | Will induce withdrawal in patients with a current dependence on opioids.<br><br>Oral naltrexone is not indicated for opioid use disorder.<br><br>Patients should be warned of the risk of hepatic injury. |

| | | | | |
|---|---|---|---|---|
| | | | hypersensitivity reaction to injectable diluents | |
| **Buprenorphine/Naloxone** | Partial mu-opioid receptor agonist | Opioid use disorder | • Hypersensitivity to buprenorphine<br><br>• Hypersensitivity to naloxone | Preferred first line over buprenorphine alone due to decreased potential for misuse. |
| **Buprenorphine long-acting injectable** | Partial mu-opioid receptor agonist | Opioid use disorder | • Hypersensitivity to buprenorphine | May improve adherence over transmucosal buprenorphine |

*Information in the table can be corroborated and expanded on by the references in this Rule. Please consult SAMHSA resources, ASAM guidelines and FDA approved medication labeling for more specific medication information.

**Suggested Medication Dosing:**

**Buprenorphine**

- Initiate and modify therapy according to current SAMHSA recommendations.
- Consideration of transitioning to long-acting buprenorphine:
  - Consult with collaborating practitioner on appropriateness of switching from transmucosal buprenorphine to long-acting injectable buprenorphine.
  - May be appropriate for patients with poor tolerance for transmucosal buprenorphine.
  - May be more convenient for some patients due to extended dosing interval.
  - Eliminates risk of diversion.
- Other considerations for buprenorphine:
  - Many formulations, including combination products.
  - Doses above 24mg do not increase respiratory effects.
  - May precipitate withdrawal in patients actively using other opioids.
  - Overdose is uncommon but may be more likely in patients with low tolerance or concurrent use of use of CNS depressants such as alcohol or benzodiazepines.
  - Toddlers who ingest any amount of buprenorphine accidentally/in an exploratory fashion are at risk of life-threatening respiratory depression. Counsel patients about safe buprenorphine storage and what to do in the case of accidental/exploratory ingestion in a toddler (call poison control and seek medical attention).

**Naltrexone**

- Initiate and modify therapy according to current SAMHSA recommendations or ASAM guidelines.
- Considerations for immediate release naltrexone:
  - o Oral naltrexone is not recommended outside of limited circumstances.
  - o Highly compliant and motivated patients.
  - o Patients unable to take ER injection.
  - o Patients who do not want to take naltrexone ER injection or opioid agonists.
  - o Naltrexone ER injection is the preferred maintenance antagonist for opioid use disorder.
  - o Initiation: ensure patient is adequately withdrawn from opioids.
- Patient should be free from short acting opioids for 6 days and/or free from long-acting opioids for 7-10 days.
  - o Extended release Dosing.
- Extended-release injectable naltrexone is given every 3-4 weeks via gluteal intramuscular injection at a dose of 380mg per injection.

- Inject one dose every 4 weeks.

- For patients that are more rapid naltrexone metabolizers, may inject one dose every 3 weeks or supplement with oral naltrexone, depending on insurance considerations and clinical factors.

**Other Medication Management:**

A qualified pharmacist in collaboration with a practitioner or entity, under this protocol may also:

- Initiate, modify, discontinue, and administer medications for the treatment of opioid withdrawal symptoms including but not limited to alpha-2 agonists, antiemetics, antihistamines, anticonvulsants, antidiarrheal agents and analgesics.
- Initiate, modify, discontinue, and administer naloxone for overdose prevention. • Initiate, modify, discontinue, and administer medications for the treatment of opioid induced side effects.

**Counseling, Monitoring and Follow-Up:**

- Pharmacists will communicate a clear follow up plan to patient and collaborating practitioner, including but not limited to next steps, what to do with medication side effects or reactions, and who to contact with concerns.
- Medication counseling for any prescribed medication is required.
- Develop a treatment and monitoring plan for MOUD, including referral to medical services, case management, behavioral and psychosocial services, substance use counseling, and other services as indicated.

**Referrals to collaborating practitioner:**

- On therapy, if patient experiences moderate to severe medication side effects.
- On therapy if patient becomes pregnant.
- Lack of efficacy and/or adherence to therapy.
- Patient resumes illicit opioid use.
- Abnormal lab results will be communicated immediately to collaborating practitioner or emergency care if patient is having a life-threatening concern.

**Documentation:**

- The pharmacist's assessment, clinical findings, and plan of care will be documented in a health record mutually accessible by the referring practitioner, collaborating practitioner, and/or primary care practitioner. If a mutually accessible health record is not available documentation will be shared via facsimile or other secured communication platform as agreed upon between collaborating practitioners.
- The pharmacist will also follow all documentation requirements set forth in Rule 17.

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**Editor's Notes**

**History**

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

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

Rule 4.00.00 eff. 11/30/2007.

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

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

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

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

Rule 15.09.11 eff. 01/31/2009.

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

Rule 9.00.00 eff. 04/30/2009.

Rules 5.00.55, 5.01.31(a), 6.00.20(f), 14.00.40, 15.01.17, 15.01.18, 15.08.19(f), 15.09.11(d), 15. 09.15, 15.09.19, 15.09.20(g-h), 15.09.23, 15.09.24, 15.10.10, 16.00.20(d), 19.01.10(b), 19.01.30(a) eff. 12/30/2009.

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

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

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

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

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

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

Rule 14.00.10 eff. 05/15/2012.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Rule 33.00.00 eff. 11/14/2023.

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

Rules 2.01.58, 3.01.30-3.01.34, 14.00.30, 14.00.50, 21.10.70, 21.10.90, 21.11.00, 21.11.10, 21.20.40, 30.00.00, 32.00.00, 33.00.00 repealed eff. 11/30/2023.

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

Rules 2.01.20 a, 3.00.30 c, 3.00.90 a, 3.00.92, 3.01.22 f, 11.04.10, 15.01.11 (9), 15.10.14 h-i, 17.00.10 a, 17.00.10 a.1, 17.00.10 d, 17.00.30 a.5, 17.00.30 a.7.b, 17.00.30 b, 21.00.20 iii, 23.00.30 e, 31.00.05, Appendix A, Appendix E eff. 11/30/2024.

Rule Appendix G eff. 03/17/2025.

Rule Appendix G eff. 05/15/2025.

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