DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

3 CCR 719-1

STATE BOARD OF PHARMACY RULES AND REGULATIONS

…

2.00.00 ORDERS.

…

Basis and Purpose: The purpose of the proposed amendment to Board Rule 2.01.20 is to both allow for the electronic maintenance of the required information within this rule and to clarify the statutory requirement of section 12-240-107(6)(a), C.R.S. which requires, among other things, that all physician assistant issued prescription orders for controlled substances detail the name of the physician assistant's supervising physician.

Authority for Promulgation of Rules: sections 12-240-107(6)(a), 12-280-101, 12-280-107, and 24-4-103, C.R.S.

Commented [KE1]: Where should this be placed? It is currently located in the middle of the rule.

2.01.20 Additional Information. The following shall also appear on the prescription or LTCF chart order, or corresponding electronic record of the prescription or LTCF chart order, when appropriate:

a. Any change in or clarification of an order shall be documented on the order and shall bear the initials of the responsible pharmacist or intern, the date contacted and the name of the individual conveying such change or clarification.

Commented [KE2]: Dan Telford: add: "or corresponding electronic order"

b. The name of supervising physician when a controlled substance order is issued by a physician assistant licensed by the Colorado Medical Board.

c~~b~~. When a substitution is made, the order shall indicate the following:

(1) The names of both the drug prescribed and the drug actually dispensed, as well as the date on which such substitution was initially made.

(2) The order shall also indicate the name of the distributor of the drug dispensed as it appears on the package or the national drug code number.

(3) On an order for a schedule II controlled substance, substitution shall not be deemed to be an alteration of the order.

(4) On subsequent refilling of any order, any change in the name of the distributor or the national drug code number as it appears on the package shall be recorded on the order unless the computer system used at that prescription drug outlet changes only the affected transaction(s) (any computer entry change must not alter previous transaction records).

d~~c~~. In the case of a chart order for a hospitalized patient (hospital chart order), the following information need not necessarily appear on the chart order, provided that such

information is recorded on another appropriate, uniformly maintained and readily retrievable permanent record which reflects:

(1) The identity of the pharmacist making the initial interpretation;

(2) The identity of the pharmacist making the final evaluation each time a drug is dispensed, if different from the pharmacist making the initial interpretation;

(3) The quantity dispensed and

(4) The date of dispensing.

(5) Any record of a controlled substance dispensed pursuant to a chart order for an individual patient shall be visually identifiable from records of non-controlled substances.

…

3.00.00 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 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.

...

3.01.00 Packaging.

…

3.01.22 Filling of automated cassettes.

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

~~b. Schedule II controlled substances may not be packaged into automated cassettes.~~

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

1. If a suitable internal record is maintained in the prescription drug outlet or other outlet, the requirements of 4, 5, 6, 7, and 8 of this Rule may be omitted from the labeling and maintained in such record. ~~An internal lot number shall be assigned and shall appear in the labeling. In a prescription drug outlet the record shall be signed by the pharmacist responsible for each lot packaged. In an other outlet the record shall be signed by the person specified in the Board approved~~

Commented [KE3]: Kim Ward (Kroger): support for these changes from the community setting, but would like clarification on whether a technician can do this?

protocol. 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 and unique identifier;

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

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

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

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

...

5.00.00 OUTLETS.

…

5.00.40 Transfer of Ownership. Application to transfer registration of an in-state or non-resident prescription drug outlet shall be submitted to the Board as provided in section 12-280-118, C.R.S., no less than thirty (30) days prior to the immediately upon the transfer of ownership, with a final notice of change submitted to the Board on the day it occurs. A transfer of ownership shall be deemed to have occurred:

a. In the event the in-state or non-resident prescription drug outlet is owned by a corporation, upon sale or transfer of twenty percent or more of the shares of said corporation to a single individual or entity.

b. In the event the in-state or non-resident prescription drug outlet is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.

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

Commented [KE4]: Kristi Mihok (Walgreens): Why do we need to add a unique identifier?

Commented [KE5]: Dan Telford: consider adding "licensed and certified" to individual.

Commented [KE6]: CV- compliance may be problematic due to the timeline of transferring ownership, especially with larger pharmacies.

d. Upon incorporation of an existing in-state or non-resident prescription drug outlet.

5.00.50 Relocation.

a. In the event of a relocation of an in-state or non-resident prescription drug outlet, the outlet shall submit an application provided by the board along with the prescribed fee no less than ~~at least~~ thirty (30) days prior to the effective date of relocation.

b. The registration of a non-resident prescription drug outlet shall become void and shall be cancelled if the non-resident prescription drug outlet relocates to a state other than that which appears on its registration. In the event the non-resident prescription drug outlet wishes to continue shipping prescriptions into Colorado, it must apply for and receive a new Colorado registration prior to such shipment.

...

7.00.00 PHARMACIST MANAGER RESPONSIBILITIES.

...

7.00.30 Compliance of Outlet:

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

~~b. The manager shall be responsible for posting the following information for each pharmacy technician working in the compounding/dispensing area:~~

~~1. Certificate indicating the technician is certified by a nationally recognized certification Board; or~~

~~2. Diploma indicating the technician has graduated from an accredited pharmacy technician training program; or~~

~~3. Documentation that the pharmacy technician has completed five hundred hours of experiential training at the pharmacy. This documentation must be certified by the pharmacist manager of the prescription drug outlet; or~~

~~4. Documentation that the pharmacy technician does not have certification from a nationally recognized certification Board, has not graduated from an accredited pharmacy technician training program, and has not completed 500 hours of experiential training at the pharmacy. Within eighteen months of beginning employment at the pharmacy, each pharmacy technician shall meet the requirements of either subparagraph 1, 2 or 3 of this Rule 7.00.30(b).~~

b~~c~~. Except as provided in sections 25.5-2.5-201 through 25.5-2.5-206, C.R.S., the pharmacist manager is responsible for ensuring that all prescription drugs and controlled substances are procured by the outlet from an entity or person registered by the Board. Any drug designated as an Investigational New Drug from the Federal Food and Drug Administration is exempt from this requirement provided the research requirements for the receipt of the product are followed and it meets the requirements of section 12-280-131(2), C.R.S.

...

Commented [KE7]: DT: consider using "no more than 30 days prior" consistently throughout.

10.00.00 EMERGENCY KITS.

…

Authority for Promulgation of Rules: Sections 12-240-107(6)(a), 12-280-101, 12-280-107 and 24-4-103, C.R.S.

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

a. chain of custody report which includes the nurses name, patient name, medication, and quantity removed;

b. has the ability to show discrepancy in count; and

c. has secured access to medications, unable to access medications without approved request, and only able to access the medication that is requested.

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

…

11.00.00 RECORDS AND RECORDKEEPING.

…

11.08.00 List of Employees – Pharmacists and Pharmacy Interns. Each prescription drug outlet shall keep and maintain on a current basis a list of every licensed pharmacist and intern who has practiced pharmacy in that outlet at any time during the previous two years, including all part-time or relief personnel. This list shall show, for each such person, the following information:

a. The printed name of the person;

b. The person's license number;

c. A sample of his/her initials and signature and any other identifying mark as affixed to any record required by law or rule; and

d. The date upon which such person began practicing pharmacy in the prescription drug outlet.

11.08.50 List of Employees – Pharmacy Technicians and Provisional Pharmacy Technicians. Each prescription drug outlet shall keep and maintain on a current basis a list of every pharmacy technician and provisional pharmacy technician who has practiced in that outlet at any time during the previous two years after original required certification date of March 30, 2020, including all part-time or relief personnel. This list shall show, for each such person, the following information:

a. The printed name of the person;

Commented [KE8]: Where should this be placed? It is currently in the middle of the rule.

b. The person's state certification number;

c. A sample of his/her initials and signature and any other identifying mark as affixed to any record required by law or rule; and

d. The date upon which such person began practicing as a pharmacy technician or provisional pharmacy technician in the prescription drug outlet.

…

14.00.00 OTHER OUTLETS.

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

a. Hospitals that do not operate registered prescription drug outlets. For such hospitals, dispensing shall be limited as provided in section 12-280-120(10), C.R.S.;

b. Federal Federally Qualified Health Centers, as defined ~~in section 1861(aa)(4) of~~by the federal "Social Security Act"~~, 42 U.S.C. sec. 1395x(aa)(4)~~;

…

14.00.40 Application Procedure.

a. Original application. Original application for registration as an other outlet shall be made on a form provided by the Board. This application shall be accompanied by the appropriate fee and two copies of the protocols.

b. Other outlet relocation.

(1) When an other outlet changes location, the outlet shall submit an application on a form provided by the Board within thirty (30) days prior to the expected outlet relocation.

(2) The consultant pharmacist for the other outlet shall submit two (2) copies of revised protocols to the Board within thirty days of relocation.

c. Change of ownerships of other outlet. Application to transfer registration of an other outlet shall be submitted on a form provided by the Board within thirty (30) days prior to the expected change of ownership, with a notice of final change submitted to the Board on the day it occurs. This application shall be accompanied by the appropriate fee and two copies of protocols. Transfer of ownership shall be deemed to have occurred:

(1) In the event the other outlet is owned by a corporation, upon sale or transfer of twenty percent or more of the shares of said corporation to a single individual or entity.

(2) In the event the other outlet is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.

(3) In the event the other outlet is owned by a limited liability company (LLC), upon sale or transfer of twenty percent or more of the membership interests.

(4) Upon incorporation of an existing other outlet.

d. Change of name of other outlet. Changes in the name of an other outlet shall be submitted to the Board on a form provided by the Board. Two copies of protocols shall be submitted to the Board within thirty days of the other outlet changing its name.

e. Change of consultant pharmacist.

(1) A new application shall be submitted to the Board within thirty days after the former consultant pharmacist ceases to be the consultant pharmacist.

(2) If an application is not submitted within thirty days, the other outlet registration shall become void and the Board shall be informed in writing by the person responsible for the overall operation of the other outlet of the disposition of all drug stock possessed by the other outlet.

(3) The other outlet registration shall be issued in the name of the consultant pharmacist. At such time as the consultant pharmacist ceases to be engaged in said position, he/she shall immediately upon knowledge thereof, notify the Board in writing. The person responsible for the overall operation of the other outlet shall immediately notify the Board in writing when the consultant pharmacist ceases to function as such.

(4) A pharmacist assuming the duties as a consultant pharmacist for an other outlet shall notify the Board in writing within seven days of assuming said position.

(5) A pharmacist assuming duties as a consultant pharmacist for an other outlet shall review the current protocols and document the review within thirty days of assuming said position. Documentation shall include the date of review and the consultant pharmacist's signature. Said documentation shall be retained with the consultant pharmacist's record of inspection or the current Board approved protocols.

...

14.05.11 A ~~county health department registered as an~~registered other outlet may distribute prescription drugs to another registered other outlet~~ owned or operated by that county health department~~. The drug shall be distributed in the original sealed container in which it was received from the wholesaler.

Commented [KE9]: WJ: consider changes from "wholesaler" to "manufacturer," or in unit dose packaging.

14.05.20 Records of distribution (casual sales) of controlled substances and prescription drugs. A ~~hospital or county health department~~registered other outlet which distributes prescription drugs and/or controlled substances shall record the following:

a. The name of the drug;

b. The strength of the drug;

c. The dosage form if appropriate;

d. The quantity of the drug;

e. The manufacturer name or NDC number of the labeler of the drug if labeled only with its generic name;

f. The date of distribution;

g. The name, and address of the distributing outlet;

h. The name, and address of the receiving practitioner or registered outlet.

i. If a controlled substance is distributed, the record shall also indicate the Drug Enforcement registration number of the distributing outlet and the receiving practitioner or registered outlet.

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

…

15.00.00 WHOLESALERS.

…

15.01.10 Requirements for Licensure.

15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(1) The name, full business address, and telephone number of the applicant;

(2) All trade or business names used by the applicant;

(3) Addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the storage, handling and distribution or prescription drugs;

(4) The type of ownership or operation (i.e., partnership, corporation, sole proprietorship, limited liability company, or government entity); and

(5) The name(s) of the owner and operator of the applicant including:

(a) If a person, the name of the person;

(b) If a partnership, the name of each partner, the name of the partnership, and the federal employer identification number (FEIN);

(c) If a corporation, the name and title of each corporate officer and director, the name of the parent company, the corporate names, the federal employer identification number of the business, and the name of the state of incorporation; and

(d) Name of the business entity. If a sole proprietorship, the full name of the sole proprietor, and the name and federal employer identification number of the business entity.

(e) If a government entity, identify the name of director and the name of the governmental agency he/she represents.

(6) If a limited liability company, the name and title of each member, federal employer identification number (FEIN) of the business, and name of parent company, if any.

(7) A list of the licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by section 12-280-304, C.R.S.

(9) Wholesalers that distribute animal health medicines exclusively must have a designated representative. However, the requirement of 15.01.11a(8) is not required. For the purpose of this Rule 15.00.00, an "animal health medicine" means a prescription drug, regardless of whether the drug is originally intended for humans or animals, that will be distributed by a wholesaler only to an animal pursuant to an order issued by a veterinarian or directly to a veterinarian authorized by law to prescribe the drug.

~~b. Changes in any information in Rule 15.01.11 shall be submitted to the Board within thirty calendar days thereof.~~

bc. Any registered wholesale drug distributor that is accredited by a Board approved accreditation body shall inform the Board, in writing, within seventy-two hours if its accreditation is:

(1) Expired;

(2) Suspended;

(3) Revoked; or

(4) Withdrawn.

cd. An out-of-state wholesaler's Colorado registration shall be deemed void and shall be cancelled if the wholesaler relocates to a state other than that which is listed on its Colorado registration. In the event the wholesaler wishes to continue distributing prescription drugs into and within Colorado, it must apply for and receive a new Colorado registration indicating its current state of residence.

de. A wholesaler's Colorado registration shall be deemed void and shall be cancelled if it was registered in Colorado using an inspection from a board-approved accreditation body and the accreditation issued by that accreditation body is revoked or withdrawn.

…

15.01.14 Change of name, location, or ownership, or designated representative.

a. Any change in the name or location of the wholesaler shall be reported to the Board on an application provided by the Board within thirty (30) prior tof such change.

b. Any change in ownership shall be reported on an application provided by the Board within fifteen calendarthirty (30) days prior tof the change, with a final notice of the ownership change reported to the Board the day of such closure. Tand the new owner(s) shall apply for a new registration from the Board and pay the appropriate fee. A change of ownership shall be deemed to have occurred:

(1) In the event the owner is a corporation, upon sale or transfer of twenty percent or more of the shares of the corporation to a single individual or entity;

(2) In the event the outlet is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.

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

(4) Upon incorporation of an existing wholesaler.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

15.01.17 When a wholesaler changes location, the outlet shall submit an application on a form provided by the Board within thirty (30) days prior to outlet relocation.

…

17.00.50 Evidence-Based Healthcare Services Pursuant to Statewide Protocol.

a. A process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does

not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

b. A statewide protocol shall, at minimum, contain the following information:

1. The nature and scope of evidence-based healthcare services appropriate for certain conditions or diagnoses, and include specific directions for the patient information to be obtained, the drug therapies to be dispensed, the specified dosage regimen, and dosage forms and route of administration which are authorized. Protocols must include criteria and specific directions pharmacists are to follow when providing evidence-based healthcare services. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol shall provide precise instruction as to what assessments are needed to be conducted and what tests are to be ordered, the criteria for ordering the assessments and tests, how the assessments and tests are to be interpreted, and what action the pharmacist is to take dependent upon the assessments and test results;

2. The pharmacist training necessary to perform the functions set forth in the statewide protocol, which shall include the following:

A. A review/update of the disease or condition and the pertinent evidence base to be used by the pharmacist;

B. The pharmacology and mechanism of action or medications;

C. The relative effectiveness of various medication options;

D. Factors and considerations required for patient-centered medication selection;

E. Assessment of advantages and disadvantages of various approved medication options;

F. Monitoring considerations of approved medications including management of potential adverse events;

G. Required patient counseling considerations for approved medications; and

H. Identification of patients that should be referred to a primary care provider (or other appropriate resource) at any point during the protocol, or at follow up, and standardized referral process (if applicable).

3. Specific instructions for responding to acute allergic or other adverse reactions, if applicable;

4. A plan of treatment guided by or based on current, objective, supportive scientific evidence as published in scientific literature that provides generally accepted standard of care in all applicable professions;

5. Specific criteria upon which a patient must not be provided care under the protocol and instead referred to the patient's primary care provider for services.

c. In conjunction with this Board Rule 17.00.50, the current Colorado statewide approved protocols are provided in Appendix A, ~~and~~ B, and C.

…

24.00.50 A pharmacist or pharmacy intern who has a substance use disorder or engages in the habitual or excessive use or abuse of alcohol ~~is addicted to, dependent on, or engages in the habitual or excessive use or abuse of intoxicating liquors~~, a habit-forming drug, or a controlled substance as defined in section 12-280-126(1)(e), C.R.S., shall seek assistance from the Diversion Program as governed by section 12-280-204, C.R.S. Such pharmacists or pharmacy interns are not eligible to enter into a confidential agreement with the Board pursuant to sections 12-280-136 and 12-30-108, C.R.S.

…

Appendix C

Colorado State Board of Pharmacy Statewide Protocol Pre-Exposure and Post-Exposure Prophylaxis of HIV

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

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

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

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

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

Records:

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

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

Pre-Exposure Prophylaxis (PrEP) Protocol

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

The pharmacist may consider and offer the patient an oral antiretroviral agent listed in Table I according to the following criteria:

- Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care fingerstick blood test, taken within 7 days. Neither oral swab testing nor patient report of negative status are acceptable for evidence.
- Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:
    - MSM (men who have sex with men)
        - Adult man
        - Without acute or established HIV infection
        - Any male sex partners in past 6 months
        - Not in a monogamous partnership with a recently tested, HIV-negative man

        AND at least one of the following
        - any anal sex without condoms (receptive or insertive) in the past 6 months
        - A bacterial STI (syphilis, gonorrhea or chlamydia) diagnosed or reported in past 6 months
    - Heterosexually Active Men and Women
        - Adult person
        - Without acute or established HIV infection

- Any sex with opposite sex partners in past 6 months
- Not in a monogamous partnership with a recently tested HIV-negative partner

AND at least one of the following

- Is a man who has sex with both women and men (behaviorally bisexual)
- Infrequently uses condoms during sex with 1 or more partners of unknown HIV status who are known to be substantial risk of HIV infection (persons who inject drugs PWID or bisexual male partner)
- Is in an ongoing sexual relationship with an HIV-positive partner
- A bacterial STI (syphilis, gonorrhea in women or men) diagnosed or reported in past 6 months

○ Persons Who Inject Drugs (PWID)

- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND at least one of the following

- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (see above)

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

- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest recent HIV infection not yet detectable (tiredness, fever, joint or muscle aches, headache, sore throat, vomiting, diarrhea, rash, night sweats, and/or enlarged lymph nodes in the neck or groin)
- CRCL < 60 ml/min

Commented [EZ10]: Deleted previous wording and inserted exact wording from CDC guidelines since some stakeholders didn't think it was following CDC criteria – It was but it was reworded slightly. Now it is word for word. Probably clearer for those reviewing. The content of this section has NOT changed with this rewording.

TABLE 1 – MEDICATION OPTIONS

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

Medication	Age/Weight	Frequency	Duration of Therapy	Notes
FTC/TDF emtricitabine 200 mg/tenofovir	≥35 kg	Once daily	Prescription issued for 30 days with no refills if	May take with or without food. Not recommended for

disoproxil fumarate 300mg (Truvada® or generic)			baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	CRCL <60 ml/min.
FTC/TAF emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert Table 5.

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

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

Test	**Frequency**	**CDC recommendations**	**Notes**
HIV	Baseline + Every 3 months	**Required**	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + At 3 mo if symptomatic. Every 6 months if asymptomatic	Recommended	If positive – refer for care

Serum creatinine	Baseline, at 3 months, and thereafter every 6 months	Recommended	If CRCL <60 ml/min, cannot use FTC/TDF If CRCL <30 ml/min cannot use FTC/TAF
Hepatitis B screening	Baseline	Recommended	If positive – refer for care
Bone health		Optional	
Need to continue PrEP	Annually	Recommended if at continued risk	Discuss with patient

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of PrEP/nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- Consistent and correct use of condoms and prevention of STIs
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of testing for HIV, renal function, hepatitis B, and sexually transmitted diseases

Documentation:

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

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care
- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: https://www.colorado.gosv/pacific/cdphe/linkage-to-care
- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.
- If a female patient becomes pregnant while on PrEP
- Usual care for any other issues, stress importance of routine primary care and health maintenance.

* What is this for?

[1] CDC. Preexposure prophylaxis for the prevention of HIV infection in the United States, 2017 update Clinical Practice Guideline. Available at: https://stacks.cdc.gov/view/cdc/53509

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

Commented [KD11]: Are there age requirements for PREP?

Commented [EZ12R11]: Not per say but the eligibility criteria say “adult”

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

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

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

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

If the following criteria are met, antiretroviral agents in Table 1 are recommended:

- The exposure must have occurred within 72 hours
- A rapid antibody CLIA waived point of care test yields a negative result for HIV. However, if a rapid test is not available, and nPEP is otherwise indicated, therapy should still be initiated.
- Exposure to a source individual known to be HIV-positive. Exposure of:
    - Vagina
    - Rectum
    - Eye
    - Mouth
    - Other mucous membranes
    - Nonintact skin
    - Percutaneous contact (e.g., injecting drugs with a contaminated needle or needle stick injury)

  WITH
    - Blood
    - Semen
    - Vaginal secretions
    - Rectal secretions

Commented [KD13]: Moved to section below

- Breast milk
- Any body fluid visibly contaminated with blood

- Exposure types with the highest risk of transmission of HIV are:
  - Needle sharing during injection drug use
  - Percutaneous needle stick
  - Receptive anal intercourse

- If exposure with a source in which the HIV status is not known, nPEP may be considered and antiretroviral agents in Table 1 may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado Statewide Protocol for Pre-Exposure Prophylaxis of HIV).

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

- Patients younger than 13 years of age.
- Patients taking any contraindicated medications per guidelines and package insert information
- Patients with baseline rapid HIV tests indicating existing HIV infection should be referred to a primary care provider.
- Patients who have a potential exposure but have been consistently adherent to PrEP
- If a child presents to the pharmacy with a request for NPEP and is potentially a victim of child abuse, child protective services MUST be contacted.

Other Considerations:

- If the case involves a sexually assaulted person, patients should also be examined and co-managed by professionals specifically trained in assessing and counseling patients and families during these circumstances (e.g., Sexual Assault Nurse Examiner [SANE] program staff). Resources may be found at https://www.ccasa.org/gethelp/health-related-organizations/

- If a child presents to the pharmacy with a request for nPEP and is potentially a victim of child abuse, child protective services MUST be contacted 1-844-CO-4-KIDS.

TABLE 1 – MEDICATION OPTIONS

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

Medication	Age/Weight	Dose	Duration of Therapy	Notes

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

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

- All efforts should be made to obtain a negative HIV test at baseline. However, the sooner PEP is initiated, the more effective it is.
- Ask the following screening question:
    - Do you have existing kidney disease, or do you know if your kidney function is decreased for any reason?
        - In this event, pharmacist should make arrangements to refer patient for a Scr blood test urgently as nephrotoxicity can occur with acute/chronic kidney disease (CrCL <60 ml/min).
- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.

- Pharmacist must make every reasonable effort to follow up with patient post-treatment regimen at 4-6 weeks and test for confirmation of HIV status and make known to patient that repeat HIV testing is recommended at 3 and 6 months as well.

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

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)
- The importance of medication adherence with relation to efficacy of nPEP
- Signs/symptoms of acute HIV infection and recommended actions
- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment
- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed
- The necessity of follow up care with a primary care provider for usual care
- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases
- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

- The pharmacist will notify the patient's primary care provider of a record of all medications prescribed. If a patient does not have a primary care provider, the pharmacist will provide the patient with a list of providers and clinics for which they may seek ongoing care.
- The pharmacist will also follow all documentation rules in 17.00

Referrals:

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

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