Basis and Purpose: The purpose of the proposed amendments to Board Rule 3.00.22 is to implement House Bill 22-1326 concerning Fentanyl Accountability and Prevention.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

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.

3.1.20 Medical Need.

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

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

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

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

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

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

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

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

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

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

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

3.1.21 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.

3.1.22 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..~~to or for the following:~~

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

~~b. A family member, friend, or other person who is in a position to assist a person who is at increased risk of experiencing or likely to experience an opiate-related drug overdose event; or~~

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

~~d. A first responder; or~~

~~e. A unit of local government.~~

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

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

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

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

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

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

~~g.~~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.

Basis and Purpose: The purpose of the proposed amendments to Board Rule 4.00.00 is to implement Senate Bill 22-116 concerning the licensure requirements of pharmacists.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

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

a. Submission of a completed application form provided by the Division of Professions and Occupation with the appropriate fee.

b. Submission of a transcript and proof of graduation from a Board-approved school or college of pharmacy or a Foreign Pharmacy Graduate Equivalency Certification.

c. Successful passage of the academic examination and Board-approved jurisprudence examination. The passing scores for these examinations are set by the examining entity. If an applicant passes only one of the required examinations, the applicant shall be required to repeat the failed examination. If, within the previous twenty-four months, the applicant has not passed both required examinations, he or she shall be required to also repeat the previously passed examination. Score transfer applicants shall complete licensure within one year from the date their scores are received by the Division of Professions and Occupations.

d. Proof of completion of 1500 intern hours completed no more than five years after graduation from a Board-approved school or college of pharmacy. If a graduate of an unapproved school or college of pharmacy, receipt of the Foreign Pharmacy Graduate Equivalency Certification. Intern hours must be obtained under one or more of the following conditions:

(1) Engaged in the practice of pharmacy under the direct supervision of a pharmacist.

(2) Directly supervised by a manufacturer as part of the curriculum of an approved school or college of pharmacy.

(3) Directly supervised by a regulated individual as part of the curriculum of an approved school or college of pharmacy. The scope of practice of the regulated individual must overlap with that of a pharmacist for the course of the hours supervised.

(4) One year of practice of pharmacy as a licensed pharmacist in another state may be accepted by the Board in lieu of the 1500 hours if the applicant has completed this year of pharmacy practice prior to taking the examination.

e. Education, training, or service gained in military services or licensure, certification, registration or enrolled in good standing through the federal government outlined in section 12-20-202~~(4)~~, C.R.S., to be accepted and applied towards receiving a license, must be substantially equivalent, as determined by the Board, to the qualifications otherwise applicable at the time of receipt of application. It is the applicant's responsibility to provide timely and complete evidence for review and consideration. Satisfactory evidence of such education, training, or service will be assessed on a case by case basis.

4.00.40 Requirements for License Transfer or Endorsement are as follows:

a. Submission of a completed application and fee to the Board designated clearinghouse for license transfer.

b. Submission of a completed application form provided by the Division of Professions and Occupations with the appropriate fee.

c. Successful passage of the Board-approved jurisprudence examination. The passing score is set by the examining entity.

d. Applicants for license transfer must have been licensed as a pharmacist for at least one year in another state or have served an Internship meeting the Colorado requirements at the time of original licensure.

e. A person duly licensed, certified, registered, or enrolled through the federal government under the conditions set forth in section 12-20-202, C.R.S., to practice pharmacy or who possesses the education, training, or service gained in military services pursuant to section 12-20-202, C.R.S., is, upon application to the Board, eligible for licensure.

~~e~~f. An applicant for licensure transfer shall apply for license transfer using a license issued by examination in another state. Such license shall be active, current, and in good standing. If the applicant holds pharmacist licenses in multiple states, all licenses must be in good standing. For the purposes of these Rules, “good standing” means that the applicant is not currently subject to active disciplinary actions in any state.

Basis and Purpose: The purpose of the proposed amendments to Board Rule 5.00.19 is to implement Senate Bill 21-094 concerning the continuation of the State Board of Pharmacy and making changes regarding the practice pharmacy.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

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

a. Proof, if available, that the facility is actively registered with the Federal Food and Drug Administration as third-party logistics provider;

b. The location, names, and titles of all principle entity officers; and

c. Verification that the facility complies with all lawful directions and requests for information from the Federal Food and Drug Administration as well as all requests for information made by the Board pursuant to this section.

Basis and Purpose: The purpose of the proposed amendment to Board Rule 7.00.10 is to clarify the reporting requirement by pharmacist managers detailing the loss of prescription drugs and controlled substances.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

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

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

(1) The actual quantity of drug lost in relation to the type of business;

(2) The specific drug lost;

(3) Whether the loss of the drug can be associated with access to those drugs by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the drug;

(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses;

(5) Whether the specific drug is a likely candidate for diversion; and

(6) Local trends and other indicators of the diversion potential of the missing drug.

Basis and Purpose: The purpose of the proposed amendments to Board Rule 14.00.00 is to implement Senate Bill 22-173 concerning the operations of telepharmacies under the limited scope of rulemaking authority provided under the bill.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

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

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

b. Federal Federally Qualified Health Centers, as defined by the federal "Social Security Act";

c. Family Planning Clinics;

d. Colleges, universities and schools (grades kindergarten through twelve) which operate a school-based clinic for students and faculty of that school. Schools must submit any contractual affiliations to the Board prior to registration;

e. Jails. A jail which obtains prescription drugs solely on the basis of individual prescription orders which have been compounded in and dispensed from a registered prescription drug outlet do not need registration;

f. County or district public health agencies;

g. Community and Rural Health Clinics, registered, certified, or licensed as such as by the Colorado Department of Public Health and Environment;

h. Ambulatory Surgical Centers licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S., that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;

i. Medical Clinics operated by a hospital that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;

j. Hospices licensed pursuant to Part 1 of Article 3 of Title 25, C.R.S., that engage in the compounding, dispensing, and delivery of drugs or devices for administration to patients while being treated in the facility;

k. Acute treatment units, registered, certified, or licensed as such by the Colorado Department of Public Health and Environment;

~~l. Telepharmacies as defined pursuant to section 12-280-103(32), C.R.S.;~~

~~m~~l. Convalescent centers registered, certified, or licensed as such by the Colorado Department of Public Health and Environment;

~~n~~m. Community Mental Health Clinic having the same meaning as set for in section 25-27.6- 102(9), C.R.S.;

~~o~~n. Behavioral Health Entity as defined in section 25-27.6-102(6), licensed pursuant to Article 27.6 of Title 25, C.R.S.; and

~~p~~o. Approved Treatment Facility that is an approved private or public treatment facility, as described in section 27-81-102(2) and (3) that adheres to the standards set forth in section 27-81-106, C.R.S.

14.00.80 Consultant pharmacist.

e. The consultant pharmacist shall inspect and document the inspection in writing as detailed in 14.00.80(d) the following other outlets at the following frequencies:

~~(3) Telepharmacies shall be inspected and visited at least once per month.~~

Basis and Purpose: The purpose of the proposed amendments to Board Rule 16.00.00 is to implement House Bill 22-1235 concerning the sunset continue regulation of veterinary practice.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

16.00.10 General Criteria. The Board may issue a limited license to the following facilities ("outlets") to purchase, possess, store and administer drugs enumerated in this Rule 16.00.00 in a manner appropriate to the outlet as authorized by law.

a. For the purpose of the capture, sedation or immobilization of animals prior to, and including, euthanasia of injured, sick, homeless, or unwanted pets and animals:

1. ~~a humane society~~ an animal shelter which is duly registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation; or

2. an animal control agency which is operated by a unit of government.

b. For the purpose of administering vaccines to animals:

1. an animal shelter which is duly registered with the Secretary of State and has been in existence and in business for at least five years in this state as a nonprofit corporation; or

2. an animal control agency which is operated by a unit of government.

16.00.20 Application Procedure.

d. Reinstatement of Limited License.

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

(1) The reinstatement application that is current at the time submitted with the required fee; and

(2) A copy of the applicant's current registration with the Drug Enforcement Administration (DEA), if applicable.

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

a. Animal or wildlife number, if available, or general description.

b. Animal or wildlife weight, if available, or estimate.

c. Amount of drug administered, and method if drug was administered for the purposes of chemical capture or control.

d. Identification of individual administering drug.

e. Amount of drug wasted (if applicable).

f. Date administered.

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

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

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

16.02.03. Outlets must demonstrate that staff are trained and capable of using the drugs as intended. ~~Staff~~ For the purposes of chemical immobilization or euthanasia, staff must demonstrate training as follows:

a. Certification of successful completion of the chemical immobilization workshop provided by the Law Enforcement Training Institute of the University of Missouri at Columbia, Missouri; or

b. Certification of successful completion of the Chemical Immobilization Workshop (the level I or III workshop) provided by the National Animal Control Association; or

c. Certification of successful completion of other training programs that provide at least 6 hours of didactic classroom instruction which covers animal behavior, drug delivery equipment, drug delivery, drugs for immobilization, calculating drug dosages, dosage guidelines, post immobilization procedures, emergencies, records, and laws and safety. In addition, the course must provide a minimum of two hours of field training on the use of instruments used for chemical immobilization. Credentials of instructors at these courses must demonstrate their knowledge, experience and expertise in the field of chemical immobilization of animals; and

d. In the case of euthanasia training, the consultant or staff veterinarian must certify that staff has received thorough and adequate training on the proper administration of the medications that comply with the dosage and routes guidelines of the American Veterinary Medical Association. Furthermore, the veterinarian must certify that he/she has provided direct supervision of staff administration of such drugs for at least 3 hours prior to staff administration without supervision.

d. In the case of euthanasia training, the consultant or staff veterinarian must certify that staff has received thorough and adequate training on the proper administration of the medications that comply with the dosage and routes guidelines of the American Veterinary Medical Association. Furthermore, the veterinarian must certify that he/she has provided direct supervision of staff administration of such drugs for at least 3 hours prior to staff administration without supervision.

17.00.00 COLLABORATIVE PHARMACY PRACTICE.

17.00.10 Definitions.

a. "Collaborative pharmacy practice agreement," or "collaborative practice agreement" (CPA), means a written and signed agreement entered into voluntarily between one or more Colorado-licensed pharmacists and one or more physicians or advanced practice nurses licensed in this state, which statement grants authority to the pharmacist or pharmacists to provide evidence-based healthcare services to one or more patients pursuant to a specific treatment protocol delegated to a pharmacist or pharmacists by the physician or advanced practice nurse with prescriptive authority. Either party may withdraw from an agreement at any time.

1. "Collaborative drug therapy management" (CDTM) is a collaborative practice agreement involving a higher level of disease complexity and/or decision making. CDTM means the review and evaluation of drug therapy regimens for patients undertaken by a pharmacist in order to provide drug therapy, monitor progress, and initiate, modify, or discontinue drug therapy. Drug therapy management may only be undertaken pursuant to an initial diagnosis made by a physician or advanced practice nurse, a valid order for the therapy or therapies to be utilized, and a written agreement, which delineates proper protocols to be used and the type of interaction that must occur between the pharmacist and the physician or advanced practice nurse. Therapeutic interchange programs in inpatient and group model integrated closed HMO settings that are approved by medical staff committees are not considered drug therapy management for purposes of these rules.

b. "Collaborative pharmacy practice agreement," or "collaborative practice agreement," may also mean a statewide drug therapy protocol, or "statewide protocol," developed by the Board, the Colorado Medical Board, and the Colorado State Board of Nursing in collaboration with the Colorado Department of Public Health and Environment for public healthcare services under which a pharmacist may have prescriptive authority as a practitioner.

c. "Evidence-based healthcare service" means a healthcare service provided by a Colorado-licensed pharmacist pursuant to a collaborative practice agreement with a Colorado-licensed prescriber or prescribers which is guided by or based on current, objective, supportive scientific evidence as published in scientific literature as opposed to anecdotal observations. Evidence-based healthcare services may include:

1. Specific services as agreed upon and defined under Rule 17.00.70(c), including but not limited to:

a. chronic disease management and optimization of therapeutic outcomes using medication therapies based on published clinical guidelines;

b. preventative services;

c. medication management and monitoring; and

d. services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of patients' symptoms, or arresting or slowing of a disease process, and include efforts to prevent, detect, and resolve medication-related problems.

2. Prescribing and consultative services pursuant to statewide protocols as defined under Rule 17.00.50 and Appendices, including but not limited to:

a. Prescribing contraceptives;

b. Prescribing smoking cessation products; and

c. Prescribing human immunodeficiency virus infection prevention medications.

d. "Prescriber", for the purpose of this Board Rule 17.00.00, means a physician who is actively and unconditionally licensed by the Colorado Medical Board or an advanced practice registered nurse with prescriptive authority who is actively and unconditionally licensed by the Colorado State Board of Nursing.

e. "Protocol" means a specific written plan for a course of medical treatment containing a written set of specific directions created by a prescriber or groups of prescribers in conjunction with the participating pharmacist(s).

17.00.30 Pharmacist Qualifications.

a. A pharmacist may enter into a collaborative pharmacy practice agreement with one or more prescriber if:

1. The pharmacist holds a current license to practice in Colorado;

2. The pharmacist is engaged in the practice of pharmacy;

3. The pharmacist has earned a Doctor of Pharmacy degree or completed at least five (5) years of experience as a licensed pharmacist;

4. The pharmacist agrees to devote a portion of his or her practice to collaborative pharmacy practice;

5. There is a process in place for the physician, advanced practice registered nurse, and pharmacist to communicate and document changes to the patient's medical record; and

6. The pharmacist carries adequate professional liability insurance in coverage of at least $1,000,000 per incident and at least $3,000,000 in aggregate.

7. Pharmacists practicing under CDTM protocols must also:

a. Meet one of the following qualifications:

1. Proof of completion of a pharmacy residency accredited by the American Society of Health Systems Pharmacists in the specialty being practiced or;

2. Proof of completion of one year of practice experience in pharmacotherapy, and forty hours of onsite supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

3. Completion of a certificate program accredited by the Accreditation Council for Pharmacy Education ("ACPE") in each area of practice, and forty hours of on-site supervised clinical practice and training in each area in which the pharmacist is choosing to practice; or

4. Completion of at least forty hours of ACPE approved continuing education regarding clinical practice and 40 hours of on-site supervised clinical practice and training in the area in which the pharmacist is choosing to practice; or

5. Current Board specialty certification from the Board of Pharmaceutical Societies; or

6. In an inpatient or group model integrated closed HMO setting, all of the following criteria shall be met:

   a. Forty hours of on-site supervised clinical practice and training in the area(s) in which the pharmacist is choosing to practice;

   b. Protocols must be approved by the health-system's medical committee, or pharmacy and therapeutics committee; and

   c. Documented competency in each area of practice in which the pharmacist is choosing to practice shall be maintained on site.

b. Licensed Colorado pharmacists practicing collaborative drug therapy management prior to August 1, 2005, must attest and certify that they were provided clinical training, experience, and oversight practicing in the disease state(s) that they work in, and the physician with whom they are currently practicing must attest that they are practicing the standard of care required for management of the specific disease. Such attestations must be on file at the site of practice. Documentation of their employment dates must be on file as proof of practice prior to August 2, 2005.

b. This Board Rule 17.00.00 shall not prevent a pharmacist or pharmacy intern from administering vaccines and immunizations pursuant to the authorization of a physician as permitted pursuant to Board Rule 19.00.00.

17.00.50 Evidence-Based Healthcare Services Pursuant to Statewide Protocol.

a. A process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

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

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

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

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

B. The pharmacology and mechanism of action or medications;

C. The relative effectiveness of various medication options;

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

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

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

G. Required patient counseling considerations for approved medications; and

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

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

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

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

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

17.00.70 Evidence-Based Healthcare Service Pursuant to a CPA Protocol (other than a statewide protocol) Agreement and Protocol with a Prescriber or Prescribers.

a. Unless a statewide protocol is in place, a pharmacist shall not enter into a collaborative pharmacy practice agreement with a prescriber if the prescriber does not have an established relationship with the patient or patients who will be served by the pharmacist under the collaborative pharmacy practice agreement.

b. A pharmacist or prescription drug outlet shall not employ a prescriber for the sole purpose of forming a collaborative practice agreement.

c. Written agreements shall contain the following information:

1. Participating pharmacist(s);

2. Participating prescriber(s) or prescriber group;

~~3. The nature and scope of evidence-based healthcare services appropriate for certain conditions or diagnoses;~~

~~4.~~3. Protocols to be employed;

~~5.~~4. Functions and activities the pharmacist or pharmacists will perform;

~~6.~~5. Method, content and frequency of communication to the prescriber;

~~7.~~6. A provision that allows the prescriber to override any action taken by the pharmacist when the prescriber deems it to be necessary;

~~8.~~7. An effective date of the agreement, and signatures of both the participating prescriber or prescribers, pharmacist or pharmacists, or authorizing prescriber or chairperson of the authorizing group or committee; and

~~9. A provision addressing how evidence-based healthcare services will be handled and communicated when the patient has more than one prescriber involved in evaluating or treating the medical condition which is the subject of the agreement.~~

d. A protocol pursuant to an agreement between a pharmacist or pharmacists and a prescriber or prescribers shall, at minimum, contain the following information:

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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. These criteria and direction may be based upon the most recent scientific literature and guidelines. If the protocol includes conducting physical assessments or ordering and evaluating laboratory or other tests, the protocol shall provide ~~precise~~ instruction as to what assessments are needed to be conducted and what tests are to be ordered~~, the criteria for ordering the assessments and tests, how the assessments and tests are to be interpreted~~, and what action or process the pharmacist is to take or follow dependent upon the assessments and test results;

~~2. The pharmacist training necessary to perform the functions set forth in the protocol;~~

~~3.~~2. Specific instructions for responding to acute allergic or other adverse reactions, if applicable;

~~4.~~3. A plan of treatment guided by or based on current, objective, supportive scientific evidence as published in scientific literature that provides the generally accepted standard of care ~~in all applicable professions;~~.

~~5.~~4. Specific criteria upon which a patient must not be provided care under the protocol and instead referred to the patient's primary care provider for services; and

~~6.~~5. An effective date of the protocol, and signatures of the authorized prescriber, prescribers, or authorizing individual on behalf of a group of prescribers..

e. Additionally to all items described above, the following applies to CDTM:

1. Drug therapy management may include:

a. Collecting and reviewing patient drug histories;

b. Obtaining and checking vital signs;

c. Ordering and evaluating the results of laboratory tests directly, related to management of the drug therapy;

~~d.~~ Initiate, modify, or discontinue drug therapy or therapies~~, when appropriate,~~ in compliance with the protocol. ~~protocol agreed upon in relation to drug therapy management;~~

~~d.~~
~~e.~~ ~~Implementing the drug therapy plan agreed upon between the prescriber(s) and the pharmacist(s), using protocols and managing the therapy according to those protocols; and~~

~~f.~~e. Provision of other healthcare services as agreed upon in the protocol ~~as relating to drug therapy management.~~

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2. CDTM protocol means a ~~specific~~ written plan for course of medical treatment containing a written set of ~~specific~~ directions created by the prescriber, groups of prescribers, hospital medical committee, pharmacist, groups of pharmacists, or a pharmacy and therapeutics committee.

   ~~a.~~ Protocols must describe the nature and scope of drug therapy management appropriate to conditions or diagnosis, and include ~~specific~~ a treatment protocol and/or direct the pharmacist to follow accepted medical standards such as peer-reviewed evidence-based guidelines or treatment algorithms. ~~Protocols must include clear criteria and specific direction for the pharmacist to follow, based on evidence-based guidelines, when implementing, monitoring, or discontinuing drug therapy or therapies.~~

   a.

   b. The protocols shall be signed and dated by the authorizing prescriber or chairperson of the authorizing group or committee.

   c. Evidence-based protocols. Protocols used by prescribers and pharmacists engaging in drug therapy management must demonstrate a plan of treatment that constitutes evidence-based medicine. This means that the plan of treatment must be guided by or based on current, objective, supportive scientific evidence as published in scientific literature rather than anecdotal observations.

f. Agreement means a written agreement between a Colorado pharmacist and a Colorado prescriber, or a group of Colorado pharmacists and Colorado prescribers. Either party may withdraw from the agreement at any time.

17.00.80 Collaborative drug therapy management requirements for all practice settings.

a. Collaborative drug therapy management may only be conducted by a pharmacist or pharmacists pursuant to an initial diagnosis made by the prescriber or prescribers, ~~a valid order for the therapy or therapies to be~~ utilized, and a written agreement, which delineates proper protocols to be used and the type of interaction that must occur between the pharmacist and prescriber.~~"~~

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

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

d. At a minimum, the written agreement for carrying out drug therapy management between prescribers and pharmacists shall be reviewed annually, and revised, if necessary.

e. Pharmacists may perform by protocol all aspects of drug therapy management referenced in 17.00.10 (~~b~~a)(1) provided the protocol complies with 17.00.70 and the pharmacist performing these functions is qualified as set forth in section 17.00.30 and working pursuant to a written agreement with an appropriate qualified prescriber.

f. Filing requirements.

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Commented [EZ3]: It was felt that this is too restrictive and doesn't allow for registries or population management which is permitted by statute

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1. Pharmacists engaging in collaborative drug therapy management must maintain a current copy of the written agreement between the prescriber and the pharmacist at the location where drug therapy management is occurring. Upon requests by the Board or its inspectors, such written agreements and general authorization plans shall be submitted to the Board.

2. Pharmacists practicing collaborative drug therapy management must also provide to the Board documentation of their successful completion of all qualification requirements as set forth below in 17.00.30 upon request. Copies of pharmacy degrees are not required. Copies of completion of residency or other education programs or certifications must be on file in the location of practice. Attestations from the supervising pharmacist or prescriber for clinical practice must be on file.

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

17.01.00 Record-Keeping Requirements.

a. Pharmacists shall maintain all records of collaborative pharmacy practice agreements, and have readily available for inspection by the Board or its inspectors at the location where evidence-based healthcare services are provided, the following:

1. A current copy of the statewide protocol;

2. The agreement and protocol entered into with a prescriber or prescribers;

3. Documentation reflecting ~~all necessary~~ pharmacist educational training as specified in either the statewide protocol or protocol entered into with a prescriber or prescribers if required; and

~~4. The scientific literature upon which the protocols pursuant to an agreement with a prescriber or prescribers are derived.~~

Commented [EZ5]: Is this necessary since the approved statewide protocols are on the Board of Pharmacy site?

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b. Records pertaining to all prescriptions dispensed pursuant to this Board Rule 17.00.00 shall comply with all provisions of Board Rules 2.00.00, 3.00.00, and 11.00.00 and, if applicable, Board Rules 20.00.00, 21.00.00, and 26.00.00.

17.02.00 Retention of Records.

a. All records of collaborative pharmacy agreements shall be retained for a minimum of three years from the last date of healthcare service. Such records shall be available for inspection by the patient, the prescriber or prescribers, the Board or its inspectors, or any other authorized local, state, or federal law enforcement or regulatory agency.

b. Records may be maintained in an alternative data retention system such as a data processing system or direct imaging system provided that:

1. The records maintained in the alternative system contain all of the information required on the manual record;

2. The data processing system is capable of producing a hard copy of the record upon the request of the Board, its representative, or of other authorized, local, state, or federal law enforcement or regulatory agencies;

3. A back-up is conducted of the data processing system every twenty-four hours; and

4. The records are immediately available for the previous two years.

17.03.00 Confidentiality.

a. The pharmacist shall provide adequate security to prevent indiscriminate or unauthorized access to confidential records. If confidential health information is transmitted through a data communication device, the confidential health information may not be accessed or maintained by the operator of the data communication device unless specifically authorized to do so by the patient.

b. Patient information is confidential and may be released only as authorized by state and federal law. All protected health information obtained and maintained, including that obtained from the physician or other providers, must be strictly controlled in accordance with the requirements of Health Insurance Portability and Accountability Act of 1996, and the HITECH Act of 2009, and other federal and state laws and rules.

17.04.00 Participation Not Mandatory

a. No person or entity, as a condition of employment, participation on an insurance provider panel, or otherwise, shall require any prescriber to participate in or authorize collaborative practice agreements.

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

18.00.00 PHARMACY PEER HEALTH ASSISTANCE PROGRAM. [Repealed eff. 03/17/2017]

19.00.00 ADMINISTRATION.

19.01.00 Vaccines and Immunizations.

19.01.10 Qualifications.

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

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.

Basis and Purpose: The purpose of the proposed amendments to Board Rule 25.00.00 is to implement House Bill 22-1246 concerning the registration of a pharmacy located within a hospice inpatient unit as a specialized prescription drug outlet.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

25.00.00 SPECIALIZED PRESCRIPTION DRUG OUTLETS.

25.00.10 Definitions.

a. "Automated device" or "AD" means a mechanical system that performs operations or activities relative to the storage, packaging, counting, labeling, and dispensing of medications, and which collects, controls, and maintains appropriate transaction information.

b. "Hospice inpatient unit" means a facility as defined in section 15.5-4-103(8), C.R.S., that is licensed pursuant to section 25-1.5-103, C.R.S.

~~b~~c. "Long term care facility" or "LTCF" means a nursing facility as defined in section 25.5-4-103(14), C.R.S., that is licensed pursuant to section 25-1.5-103, C.R.S. An LTCF is a nursing home, skilled nursing facility or a nursing care facility that provides supportive, therapeutic, or compensating services with the availability of a licensed nurse for observation and treatment on a twenty-four hour basis.

~~c~~d. "Managing prescription drug outlet" means the prescription drug outlet located within the State of Colorado which is responsible for ownership and operation of a specialized prescription drug outlet located at an LTCF or hospice inpatient unit within Colorado. The managing prescription drug outlet is responsible for the application for the specialized prescription drug outlet on behalf of the LTCF or hospice inpatient unit. The managing prescription drug outlet shall own and operate the SPDO and maintain ownership of the drugs.

~~d~~e. "Specialized prescription drug outlet" or "SPDO" means an outlet located at an LTCF or hospice inpatient unit which is owned and operated by a managing prescription drug outlet located within the State of Colorado. The managing prescription drug outlet engages in the compounding, dispensing, and delivery of drugs and devices, or the provision of pharmaceutical care, residents of the LTCF or hospice inpatient unit. The managing prescription drug outlet may use automated devices in the SPDO to provide drugs, as well as other Board-approved nontraditional methods, to provide pharmaceutical care to the residents of the LTCF or hospice inpatient unit.

~~e~~f. "Stock drugs" mean non-patient specific prescription drugs or controlled substances that are distributed from a managing prescription drug outlet to a SPDO by means other than a patient-specific prescription order or LTCF chart order.

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

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

25.00.18 Policy and Procedure Manual.

a. Each managing prescription drug outlet and corresponding SPDO shall maintain a policy and procedure manual which is approved by the Board or its designee prior to SPDO operation. This policy and procedure manual shall be reviewed, signed, and dated by both the pharmacist manager of the managing prescription drug outlet and the nursing home or hospice inpatient unit administrator or other accountable individual of the SPDO at least once annually. The pharmacist manager shall be responsible for assuring that the nursing home or hospice inpatient unit administrator or other accountable individual of the SPDO signs the policy and procedure manual.

b. If a change in the pharmacist manager, ~~or~~ nursing home or hospice inpatient unit administrator or other accountable individual at the SPDO occurs, the new pharmacist manager and/or nursing home or hospice inpatient unit administrator or other accountable individual shall review, sign, and date the policy and procedure manual within thirty days of assuming the respective positions. The pharmacist manager shall be responsible for assuring that the new nursing home administrator or other accountable individual of the SPDO signs the policy and procedure manual.

25.00.24 Closure.

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

Basis and Purpose: The purpose of the proposed addition of Board Rule 31.00.00 is to implement Senate Bill 22-173 concerning the operations of telepharmacies under the limited scope of rulemaking authority provided under the bill.

Authority for Promulgation of Rules: Sections 12-280-101, 12-280-107(2), 12-280-108(3)(b), and 24-4-103, C.R.S.

31.00.00 Telepharmacies.

31.00.05 Definitions.

a. "Area of need" means any health facility licensed or certified by the Department of Public Health and Environment pursuant to section 25-1.5-103(1) or any area where a demonstration of need is approved by the Board.

b. "Central pharmacy" means a registered prescription drug outlet located in Colorado which is responsible for overseeing the operation of no more than three (3) telepharmcies..

c. "Telepharmacy" has the same meaning as set forth in section 12-280-103(50).

31.00.10. Application Requirements.

31.00.11 Registration. The applicant for registration shall obtain the appropriate form as approved by the Board to register a telepharmacy. In the case of an application for a new telepharmacy, for a transfer of ownership of a telepharmacy, or for the relocation of a telepharmacy, the applicant shall submit such additional documentation as the Board may require.

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

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

31.00.30 Transfer of Ownership. Application to transfer registration of a telepharmacy shall be submitted to the Board as provided in section 12-280-118, C.R.S., within thirty (30) days of the transfer of ownership. A transfer of ownership shall be deemed to have occurred:

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

b. In the event the telepharmacy is owned by a partnership, upon sale or transfer of twenty percent or more of any ownership interest.

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

d. Upon incorporation of an existing telepharmacy.

Commented [KD1]: Add language of technician limitations, even if same as in statute/rule elsewhere

Commented [KD2]: 2 per board members

31.00.40 Relocation. In the event of a relocation of a telepharmacy shall submit an application provided by the board along with the prescribed fee no more than thirty (30) days prior to the effective date of relocation.

31.00.50 Reinstatement of a Telepharmacy Registration.

a. If a registration has expired, a telepharmacy seeking to reinstate such registration shall submit the following:

(1) The current reinstatement application with the required fee;

(2) If the owner of the telepharmacy is a corporation, submit either a copy of the articles of incorporation as they were filed with the Colorado Secretary of State or a Certificate of Good Standing issued by the Colorado Secretary of State;

(3) A letter stating whether the corporation is public or private as follows:

(A) If the corporation is a public corporation, submit a list of all stockholders owning five percent or more of the stock; or

(B) If the corporation is a private corporation, submit a list of all stockholders;

(4) An accurate drawn-to-scale floor plan of the telepharmcy's compounding / dispensing area detailing all counters, bays, sinks, refrigerators and, if applicable, sterile and non-sterile compounding hoods; and

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

31.00.60 Closure.

a. Closure shall mean the permanent cessation of the practice of pharmacy in any telepharmcy.

b. Upon the closure of any telepharmacy, it shall be the responsibility of the last pharmacist manager of record to remove the orders, if applicable, to another telephamacy or prescription drug outlet where patrons and/or practitioners are afforded reasonable access to a pharmacist's interpretation of such orders. Such relocation of records shall be made within seventy-two hours after closure. The pharmacist manager shall submit a notice, on a form and manner approved by the Board, detailing the closure of the telepharmacy within seventy-two hours after closure. If the last pharmacist manager of record fails to relocate the records as required herein, the Board may direct the removal of the records to a suitable location. The last pharmacist manager of record shall make a reasonable effort to inform patrons of the telepharmacy of the location of the records.

c. The Board on request shall provide the owner of any telepharmacy an instruction sheet applicable to the transaction prior to closure, or conducting bankruptcy proceedings, or transferring or selling the prescription drug inventory.

31.01.00 Structural Requirements.

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

a. The principal compounding/dispensing area shall not be less than 150 continuous square feet.

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

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

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

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

c. All compounding/dispensing areas shall be well-lighted and well-ventilated with clean and sanitary surroundings devoted primarily to compounding/dispensing or drug storage. These areas shall provide necessary protection for drugs, chemicals and devices from deterioration due to light, heat or evaporation and shall be arranged to protect all prescription drugs and devices from pilferage or other unauthorized removal. No areas shall be subject to any condition likely to lead to errors.

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

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

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

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

e. In the principal compounding/dispensing area there shall be a sink, equipped with running hot and cold water, which is attached to an approved drain, waste and vent system, or to a portable enclosed tank which is emptied as frequently as necessary.

f. The telepharmacy shall have all the technical equipment necessary for the appropriate compounding and dispensing it conducts and as required pursuant to section 12-280-103(50)..

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

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

i. Every telepharmacy shall display in the principal compounding/dispensing area the report of the most recent inspection conducted by the Board or a photocopy of the most recent self-inspection performed by the pharmacist manager using the form provided by the Board, whichever is more recent, and have readily available documents sent or provided by the Board to clarify or assist in the legal operation of the telepharmacy.

31.02.00 Staffing and Training Requirements. Only a Colorado licensed pharmacist, Colorado-licensed pharmacy intern, or Colorado-certified pharmacy technician may engage in the practice of pharmacy. All personnel engaged in the practice of pharmacy shall be adequately trained to, as applicable to the practice setting, dispense and compound prescriptions and administer vaccines.

Commented [KD3]: Only licensed or certified individuals

31.03.00 Pharmacist Manager or Licensed Pharmacist Delegate Visitation Requirements. The pharmacist manager or licensed pharmacist delegate shall visit the telepharmacy at least once monthly. Documentation of these visits shall be readily available and retrievable for inspection at the telepharmacy upon the request of the Board or its representatives for at least two years preceding the request.

Commented [KD4]: Absolute minimum

31.04.00 ~~Operation, Staffing and Structural Requirements~~ ~~Security.~~ Security In every telepharmacy, all compounding/dispensing areas shall comply with this regulation.

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

b. In the event a pharmacist or Board-certified pharmacy technician is within the building but absent from a compounding/dispensing area, it is the responsibility of the pharmacist or Board-certified pharmacy technician to ensure the proper safeguard of all drugs.

c. If a compounding/dispensing area is continually attended by a pharmacist or Board-certified pharmacy technician when other people are in the building, the compounding/dispensing area need not be enclosed. However, if other people are in the building when there is not a pharmacist or Board-certified pharmacy technician present, every compounding/dispensing area must be enclosed by a barrier as specified in paragraph e below unless the prescription drug outlet qualifies for the exemption provided under Rule 31.04.00(a).

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

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

f. All entrances to every compounding/dispensing area shall be secured from unauthorized entry when the pharmacist or Board-certified pharmacy technician leaves the building except as provided in Rule 5,01.50(a). No one other than a Board-certified pharmacy technician shall be permitted to enter any compounding/dispensing area containing drugs, devices or patient information except in extreme emergencies, which shall be defined as a threat to property, public disaster or other catastrophe whereby the public is better served by overlooking the security restrictions of drugs and devices. If any compounding/dispensing area containing drugs, devices or patient information is opened in the absence of a pharmacist or Board-certified pharmacy technician or left unsecured from unauthorized entry when the pharmacist or Board-certified pharmacy technician

leaves the building, the pharmacist manager shall notify the Board in writing within ten days of the discovery of the occurrence. This written notice shall state:

(1) The name of the person authorizing the opening of the compounding/dispensing area if known, or the name of the pharmacist responsible for securing the compounding/dispensing area from unauthorized entry;

(2) The name of the person opening the compounding/dispensing area if known; and

(3) A description of the situation requiring opening of the compounding/dispensing area including the date and time of the opening.

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

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

DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

3 CCR 719-1

STATE BOARD OF PHARMACY RULES AND REGULATIONS

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

…

Appendix A

Colorado State Board of Pharmacy Approved Statewide Protocol for Prescribing ~~Hormonal Contraceptive Patches and Oral~~ Contraceptives

(Appendix A)

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

Definitions

(1) "Clinical visit" means a consultation with a healthcare provider, other than a pharmacist, for women's health, which should address contraception and age-appropriate screening.

(2) "Hormonal contraceptive patch" means a transdermal patch applied to the skin of a patient, by the patient or by a practitioner, that releases a drug composed of a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.

(3) "Oral hormonal contraceptive" means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may take orally.

(4) "Vaginal ring" means a plastic ring, inserted vaginally by the patient that releases a combination or hormones that is approved by the United States Food and Drug Administration to prevent pregnancy.

(5) "DPMA" means Depot Medroxyprogesterone Acetate, an muscular injection, administered every three months by a pharmacist of patient that is appr by the United States Food and Drug Administration to prevent pregnancy.

Training Program

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

Commented [KE1]: KT: Would this include emergency contraception pills (levonorgesterel and ulispristal acetate...with the latter requiring a prescription usually)?

Commented [KE2]: EZ: Would this be administered intramuscularly and subcutaneously?

Commented [KE3]: RK: Suggestion – "may prescribe" rather than dispense or administer.

Age Requirements

A pharmacist may prescribe hormonal ~~contraceptive patches and self-administered oral hormonal~~ contraceptives to a person who is at least 18 years of age.

Further Conditions

(1) For each new patient requesting a contraceptive service and, at a minimum of every twelve months for each returning patient, a participating pharmacist must:

(a) Obtain a completed Colorado Self-Screening Risk Assessment Questionnaire;

(b) Utilize and follow the Colorado Standard Procedures Algorithm to perform the patient assessment;

(c) Prescribe, if clinically appropriate, the hormonal contraceptive patch~~, or~~ self-administered oral hormonal contraceptive, DMPA, Vaginal Ring, or refer to a healthcare practitioner;

(d) Provide the patient with a Visit Summary;

(e) Advise the patient to consult with a primary care practitioner or women's health care practitioner;

(f) Refer any patient that may be subject to abuse to an appropriate social services agency; and

(g) Ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality.

(2) If the ~~hormonal contraceptive patch or self-administered oral hormonal~~ contraceptive is dispensed or administered, it must be done as soon as practicable after the pharmacist issues the prescription and shall include any relevant educational materials.

(3) A pharmacist must not~~:~~:

(a) Require a patient to schedule an appointment with the pharmacist for the prescribing or dispensing of a hormonal contraceptive ~~patch or self-administered oral hormonal contraceptive~~;

(b) Continue to prescribe and dispense a hormonal contraceptive to a patient beyond three years from the initial prescription without evidence of a clinical visit; or

(c) Prescribe in instances that the Colorado Standard Procedures Algorithm requires referral to a provider.

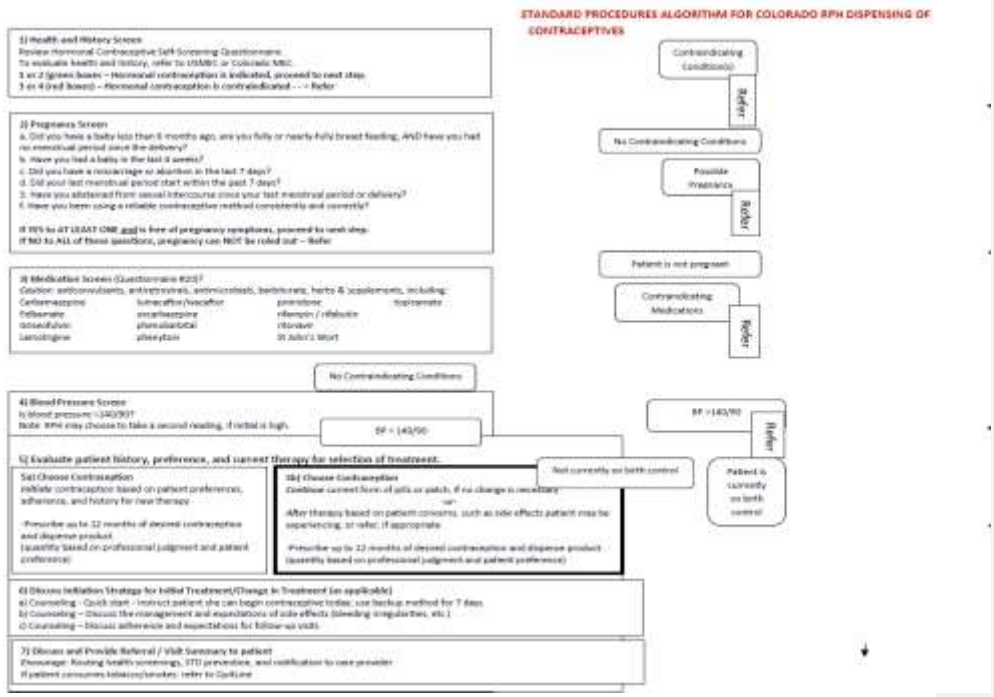
(4) Records:

(a) Pursuant to Pharmacy Rule 17.00.50, a process shall be in place for the pharmacist to communicate with the patient's primary care provider and document changes to the patient's medical record. If the patient does not have a primary care provider, or is unable to provide contact information for his or her primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult an appropriate health care professional of the patient's choice.

Commented [KE4]: KT/GM: Consider revising the wording – May prescribe or refer to a healthcare practitioner. Or list all forms of contraceptives.

Commented [KE5]: VE/EZ: Suggest language that creates flexibility between pharmacists and patients. Appointments should be allowed, but not required. GM: Consider striking (3)(a).

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


STANDARD PROCEDURES ALGORITHM FOR COLORADO RPH DISPENSING OF CONTRACEPTIVES
1) Health and History Screen
Review Hormonal Contraceptive Self-Screening Questionnaire
To evaluate health and history, refer to USMEC or Colorado MEC
1 or 2 (green boxes – Hormonal contraception is indicated, proceed to next step.
3 or 4 (red boxes) – Hormonal contraception is contraindicated - - - > Refer
Contraindicating condition(s)
Refer
2) Pregnancy Screen
a. Did you have a baby less than 6 months ago, are you fully or nearly fully breast feeding, AND have you had no menstrual period since the delivery?
b. Have you had a baby in the last 4 weeks?
c. Did you have a miscarriage or abortion in the last 7 days?
d. Did your last menstrual period start within the past 7 days?
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?
f. Have you been using a reliable contraceptive method consistently and correctly?
If YES to AT LEAST ONE and is free of pregnancy symptoms, proceed to next step.
If NO to ALL of these questions, pregnancy can NOT be ruled out – Refer
No Contraindicating Conditions
Possible Pregnancy
Refer
3) Medication Screen (Questionnaire #2)?
Caution: anticonvulsants, antiretrovirals, antimicrobials, barbiturate, herbs & supplements, including:
Carbamazepine
felbamate
oxcarbazepine
phenobarbital
phenytoin
rifampin / rifabutin
ritonavir
St John's Wort
topiramate
Patient is not pregnant
Contraindicating Medications
Refer
No Contraindicating Conditions
4) Blood Pressure Screen
b) blood pressure: <140/90?
Note: RPH may choose to take a second reading, if initial is high.
BP < 140/90
BP >140/90
Refer
5) Evaluate patient history, preference, and current therapy for selection of treatment.
Not currently on birth control
Patient is currently on birth control
5a) Choose Contraception
Initiate contraception based on patient preferences, adherence, and history for new therapy
- Prescribe up to 12 months of desired contraceptive and dispense product (quantity based on professional judgment and patient preference)
5b) Choose Contraception
Continue current form of pills or patch, if no change is necessary
-or-
After therapy based on patient concerns, such as side effects patient may be experiencing, or refer, if appropriate
- Prescribe up to 12 months of desired contraceptive and dispense product (quantity based on professional judgment and patient preference)
6) Discuss Initiation Strategy for Initial Treatment/Change in Treatment (as applicable)
a) Counseling - Quick start - Instruct patient she can begin contraceptive today; use backup method for 7 days
b) Counseling – Discuss the management and expectations of side effects (bleeding irregularities, etc.)
c) Counseling – Discuss adherence and expectations for follow-up visits
7) Discuss and Provide Referral / Visit Summary to patient
Encourage: Routine health screenings, STD prevention, and notification to care provider
If patient consumes tobacco/smokes: refer to QuitLine

Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Pages 1,2 .....Color coded in the left column to match the corresponding question of the Oregon Self-Screening Risk Assessment Questionnaire.

Pages 3,4 .....Arranged alphabetically by disease state

Key:	
1 No restriction (method can be used)	
2 Advantages generally outweigh theoretical or proven risks	
3 Theoretical or proven risks usually outweigh the advantages	
4 Unacceptable health risk (method not to be used)	

Corresponding to the order of the Colorado Self-Screening Contraception Risk Assessment Questionnaire:

Condition	Sub-condition	Combined pill, patch		Progestin-only pill		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	
a. Age		Menarche to <40=1		Menarche to <18=1		Yes
		>40=2		18-45=1		Yes
				45=1		Yes
b. Smoking	a) Age < 35	2		1		Yes
	b) Age > 35, < 15 cigarettes/day	3		1		Yes
	c) Age > 35, >15 cigarettes/day	4		2		Yes
c. Pregnancy	(Not Eligible for contraception)	NP*		NP*		NP*
d. Postpartum (nonbreastfeeding women)	a)< 21 days	4		1		Yes
	b)21 days to 42 days:					
	(i) with other risk factors for VTE	3*		1		Yes
	(ii) without other risk factors for VTE	2		1		Yes
	c)> 42 days	1		1		Yes
e. Breastfeeding	a) <21 days postpartum	4*		3*		Yes
	b) 21to <30 days postpartum					
	(i) with other risk factors for VTE	3*		2*		Yes
	(ii) without other risk factors for VTE	2*		2*		Yes
	c) 30-42 days postpartum					
	(i) with other risk factors for VTE	3*		1*		Yes
	(ii) without other risk factors for VTE	2*		1*		Yes
	d) >42 days postpartum	2*		1*		Yes
f. Diabetes mellitus(DM)	a) History of gestational DM only	1		1		Yes
	b) Non-vascular disease					
	b) Other abnormalities					

	(i) non-insulin dependent	2	2	Yes
	(ii) insulin dependent‡	2	2	Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*	3	Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*	3	Yes
g. Headaches	a) Non-migraine (mild or severe)	1*	1	Yes
	b) Migraine			
	(i without aura (includes menstrual migraine)	2*	2	Yes
	(ii) with aura	4*	3	Yes
h. Hypertension	a) Adequately controlled hypertension	3*	3*	Yes
	b) Elevated blood pressure levels (properly taken measurements):			
	(i) systolic 140-159 or diastolic 90-99	3	3	Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4	3	Yes
	c) Vascular disease	4	3	Yes
i. History of high blood pressure during pregnancy		2	1	Yes
j. Hyperlipidemias		2/3*	2*	Yes
k. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiacfunction:			
	(i) < 6 months	4	3	Yes
	(ii) > 6 months	3	2	Yes
	b) Moderately or severely impaired cardiac function	4	3	Yes
l. Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension)	3/4*	3*	Yes
m. Ischemic heart disease‡	Current and history of	4	3 / 4	Yes
n. Valvular heart disease	a) Uncomplicated	2	2	Yes
	b) Complicated‡	4	3	Yes
o. Stroke‡	History of cerebrovascular accident	4	3 / 4	Yes
p. Thrombogenic mutations‡		4*	3*	Yes
q. Deep venous thrombosis (DVT) & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy			
	(i) higher risk for recurrent DVT/PE	4	3	Yes
	ii) lower risk for recurrent DVT/PE	3	2	Yes
	b) Acute DVT/PE	4	3	Yes

	c) DVT/PE and established on anticoagulant therapy for at least 3 months:			
	i) higher risk for recurrent DVT/PE	4[a]	2	Yes
	ii) lower risk for recurrent DVT/PE	3[a]	2	Yes
	d) Family history (first-degree relatives)	2	1	Yes
	e) Major surgery			
	(i) with prolonged immobilization	4	2	Yes
	(ii) without prolonged immobilization	2	1	Yes
	f) Minor surgery without immobilization	2	1	Yes
c. History of bariatric surgery‡	a) Restrictive procedures	1	1	Yes
	b) Malabsorptive procedures	2[a],[c]	2	Yes
c. Breast disease & Breast Cancer‡	a) Undiagnosed mass	2[a]	2[a]	Yes
	b) Benign breast disease	1	1	Yes
	c) Family history of cancer	1	1	Yes
	d) Breast cancer: ‡			
	i) current	4	4	Yes
	ii) past and no evidence of current disease for 5 years	3	3	Yes
f. Viral hepatitis	a) Acute or flare	4[a],[c]	2	2	Yes
	b) Carrier/Chronic	2	2	2	Yes
g. Cirrhosis	a) Mild (compensated)	2	2	Yes
	b) Severe (decompensated)	4	4	Yes
h. Liver tumors	a) Benign:			
	i) Focal nodular hyperplasia	2	2	Yes
	ii) Hepatocellular adenoma‡	4	3	Yes
	b) Malignant‡	4	4	Yes
i. Gallbladder disease	a) Symptomatic:			
	(i) treated by cholecystectomy	2	2	Yes
	(ii) medically treated	2	3	Yes
	(iii) current	3	2	Yes
	b) Asymptomatic	2	2	Yes
j. History of Cholestasis	a) Pregnancy-related	2	2	Yes
	b) Past COC-related	3	2	Yes
k. Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4	4	Yes
	b) Severe thrombocytopenia	2	2	Yes
	c) Immunosuppressive treatment	2	2	Yes
	d) None of the above	2	2	Yes

r. Rheumatoid arthritis	a) On immunosuppressive therapy	1	1	Yes
	b) Not on immunosuppressive therapy	2	1	Yes
ss. Blood conditions & Anemias	a) Thalassemia	1	1	Yes
	b) Sickle Cell Disease8	1	1	Yes
	c) Iron-deficiency anemia	1	1	Yes
tt. Epilepsy9	(see also Drug Interactions)	1*	1*	Yes
uu. Tuberculosis10 (see also Drug Interactions)	a) Non-pelvic	1*	1*	Yes
	b) Pelvic	1*	1*	Yes
vv. HIV	High risk	1	1	Yes
	HIV infected (see also Drug Interactions)11	1*	1*	Yes
	AIDS (see also Drug Interactions)11	1*	1*	Yes
	Clinically well on therapy	If on treatment, see Drug Interactions		
ww. Antiretroviral therapy	a) Nucleoside reverse transcriptase inhibitors	1*	1	Yes
	b) Non-nucleoside reverse transcriptase inhibitors	2*	2*	Yes
	c) Ritonavir-boosted protease inhibitors	3*	3*	Yes
xx. Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3*	3*	Yes
	b) Lamotrigine	3*	1	Yes
yy. Antimicrobial therapy	a) Broad spectrum antibiotics	1	1	Yes
	b) Antifungals	1	1	Yes
	c) Antiparasitics	1	1	Yes
	d) Rifampicin or rifabutin therapy	3*	3*	Yes
Anemias	a) Thalassemia	1	1	Yes
	b) Sickle cell disease8	1	1	Yes
	c) Iron-deficiency anemia	1	1	
Benign ovarian tumors	(including cysts)	1	1	Yes
Breast disease/ Breast Cancer	a) Undiagnosed mass	2*	2*	Yes
	b) Benign breast disease	1	1	Yes
	c) Family history of cancer	1	1	Yes
	d) Breast cancer8b			
	i) current	4	4	Yes
	ii) past and no evidence of current disease for 5 years	2	2	Yes
Cervical cancer	Awaiting treatment	3	1	Yes
Cervical ectropion		1	1	Yes

Cervical intraepithelial neoplasia		2	1	Yes
Cirrhosis	a) Mild (compensated)	1	1	Yes
	b) Severe(8) (decompensated)	4	2	Yes
Cystic Fibrosis		1*	1*	Yes
Deep venous thrombosis (DVT) / & Pulmonary embolism (PE)	a) History of DVT/PE, not on anticoagulant therapy			
	i) higher risk for recurrent DVT/PE	4	2	Yes
	ii) lower risk for recurrent DVT/PE	3	2	Yes
	b) Acute DVT/PE	4	2	Yes
	c) DVT/PE and established on anticoagulant therapy for at least 3 months			
	i) higher risk for recurrent DVT/PE	3*	2	Yes
	ii) lower risk for recurrent DVT/PE	2*	2	Yes
	d) Family history (first-degree relatives)	2	1	Yes
	e) Major surgery			
	(i) with prolonged immobilization	4	2	Yes
	(ii) without prolonged immobilization	2	1	Yes
	f) Minor surgery without immobilization	1	1	Yes
Depressive disorders			1*	Yes
Diabetes mellitus (DM)	a) History of gestational DM only	1	1	Yes
	b) Non-vascular disease			
Diabetes mellitus (cont.)	(i) non-insulin dependent	2	2	Yes
	(ii) insulin dependent(8)	2	2	Yes
	c) Nephropathy/ retinopathy/ neuropathy(8)	3/4*	2	Yes
	d) Other vascular disease or diabetes of >20 years' duration(8)	3/4*	2	Yes
Endometrial cancer(8)		1	1	Yes
Endometrial hyperplasia		1	1	Yes
Endometriosis		1	1	Yes
Epilepsy(8)	(see also Drug Interactions)	1*	1*	Yes
Gallbladder disease	a) Symptomatic			
	(i) treated by cholecystectomy	2	2	Yes
	(ii) medically treated	3	2	Yes
	(iii) current	3	2	Yes
	b) Asymptomatic	2	2	Yes
Gestational trophoblastic disease	a) Decreasing or undetectable s-hCG levels	1	1	Yes
	b) Persistently elevated s-hCG levels or malignant disease(8)	1	2	Yes
Headaches	a) Non-migrainous	1* 2*	1* 1*	Yes

	b) Migraine					
	i) without aura, age <35	2*	3*	1*	2*	Yes
	ii) without aura, age >35	3*	4*	1*	2*	Yes
	iii) with aura, any age	4*	4*	1*	3*	Yes
History of bariatric surgery	a) Restrictive procedures	1		1		Yes
	b) Malabsorptive procedures	Delay 6		3		Yes
		1(3) 1				
History of cholestasis	a) Pregnancy-related	2		1		Yes
	b) Past COC-related	3		2		Yes
History of high blood pressure during pregnancy		2		1		Yes
History of pelvic surgery		1		1		Yes
HIV	High risk	1*		1*		Yes
	HIV infected (see also Drug Interactions)[6]	1*		1*		Yes
	AIDS (see also Drug Interactions)[6]	1*		1*		Yes
	Clinically well on therapy	If on treatment, see Drug Interactions.				
Hyperlipidemias		2/3*		2*		Yes
Hypertension	a) Adequately controlled hypertension	3*		1*		Yes
	b) Elevated blood pressure levels					
	(i) systolic 140-159 or diastolic 90-99	3		1		Yes
	(ii) systolic ≥160 or diastolic ≥100[6]	4		2		Yes
	c) Vascular disease	4		2		Yes
Inflammatory bowel disease	(Ulcerative colitis, Crohn's disease)	2/3*		2		Yes
Ischemic heart disease[6]	Current and history of	4	2	3		Yes
Liver tumors	a) Benign					
	i) Focal nodular hyperplasia	2		2		Yes
	ii) Hepatocellular adenoma[4]	4		4		Yes
	b) Malignant[4]	4		4		Yes
Malaria		1		1		Yes
Multiple risk factors for arterial cardiovascular disease	(such as older age, smoking, diabetes and hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		Yes

Multiple sclerosis	a) with prolonged immobility	4	1	Yes
	b) without prolonged immobility	1	1	Yes
Obesity	a) >30 kg/m2 body mass index (BMI)	2	1	Yes
	b) Menarche to < 18 years and > 30 kg/m2 BMI	2	1	Yes
Ovarian cancer‡		1	1	Yes
Parity	a) Nulliparous	1	1	Yes
	b) Parous	1	1	Yes
Past ectopic pregnancy		1	1	Yes
Pelvic inflammatory disease	a) Past, (assuming no current risk factors of STIs)			
	(i) with subsequent pregnancy	1	1	Yes
	(ii) without subsequent pregnancy	1	1	Yes
	b) Current			
Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function			
	(i) < 6 months	4	1	Yes
	(ii) > 6 months	3	1	Yes
	b) Moderately or severely impaired cardiac function	4	2	Yes
Postabortion	a) First trimester	1*	1*	Yes
	b) Second trimester	1*	1*	Yes
	c) Immediately post-septic abortion	1*	1*	Yes
Pregnancy		NA*	NA*	NA*
Rheumatoid arthritis	a) On immunosuppressive therapy	2	1	Yes
	b) Not on immunosuppressive therapy	2	1	Yes
Schistosomiasis	a) Uncomplicated	1	1	Yes
	b) Fibrosis of the liver‡	1	1	Yes
Severe dysmenorrhea		1	1	Yes
Sexually transmitted infections (STIs)	a) Current purulent cervicitis or chlamydial infection or gonorrhea	1	1	Yes
	b) Other STIs (excluding HIV and hepatitis)	1	1	Yes
	c) Vaginitis (including trichomonas vaginalis and bacterial vaginosis)	1	1	Yes
	d) Increased risk of STIs	1	1	Yes
Smoking	a) Age < 35	2	1	Yes
	b) Age > 35, < 15 cigarettes/day	3	1	Yes
	c) Age > 35, >15 cigarettes/day	4	1	Yes
Solid Organ transplantation‡	a) Complicated	4	2	Yes
	b) Uncomplicated	2*	2	Yes
Stroke‡	History of cerebrovascular accident	4	2	Yes

Superficial venous thrombosis	a) Varicose veins	1	1	Yes
	b) Superficial thrombophlebitis	1	1	Yes
Systemic lupus erythematosus‡	a) Positive (or unknown) antiphospholipid antibodies	4	4	Yes
	b) Severe thrombocytopenia	2	2	Yes
	c) Immunosuppressive treatment	2	2	Yes
	d) None of the above	1	1	Yes
Thrombogenic mutations‡		4*	2*	Yes
Thyroid disorders	Simple goiter/ hyperthyroid/hypothyroid.	1	1	Yes
Tuberculosis‡ (see Drug Interactions)	a) Non-pelvic	1*	1*	Yes
Unexplained vaginal bleeding	b) Pelvic	1*	1*	Yes
	(suspicious for serious condition) before evaluation	2*	2*	Yes
Uterine fibroids	a) Uncomplicated	1	1	Yes
	b) Complicated‡	4	1	Yes
Vaginal bleeding patterns	a) Irregular pattern without heavy bleeding	1	1	Yes
	b) Heavy or prolonged bleeding	1*	1*	Yes
Viral hepatitis	a) Acute or flare	3/4* 1	1	Yes
	b) Carrier/Chronic	1	1 1	Yes
DRUG INTERACTIONS				
Antiretroviral therapy (All other ARVs are 1 or 2 for all methods)	Fosamprenavir (FPV)	3*	2*	Yes
Anticonvulsant therapy	a) Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbacepine)	3*	3*	Yes
	b) Lamotrigine	3*	1	Yes
Antimicrobial therapy	a) Broad spectrum antibiotics	1	1	Yes
	b) Antifungals	1	1	Yes
	c) Antiparasitics	1	1	Yes
	d) Rifampicin or rifabutin therapy	3*	3*	Yes
SSRIs		1	1	Yes
St. John's Wort		2	2	Yes

Hormonal Contraceptive Self-Screening Questionnaire

Name_____ Health Care Provider's Name _____ Date _____
Date of Birth _____ Age* _____ Weight _____ Do you have health insurance? Yes / No
What ws the date of your last women's health clinical visit? _____
Any Allergies to Medications? *Yes / No* If yes, list them here: _____
Background Information:

1	Do you think you might be pregnant now?	Yes □ No□
2	What was the first day of your last menstrual period?	___/___/___
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection? Have you previously had contraceptives prescribed to you by a pharmacist?	Yes □ No □ Yes □ No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No□
	- If yes, what kind of reaction occurred?	
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes □ No□
	- If yes, which one do you use?	
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No□
5	Do you smoke cigarettes?	Yes □ No□

Medical History:

6	Have you given birth within the past 6 weeks?	Yes □ No□
7	Are you currently breastfeeding?	Yes □ No□
8	Do you have diabetes?	Yes □ No□
9	Do you get migraine headaches? If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes □ No□
10	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No□
11	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No□
12	Have you ever had a blood clot?	Yes □ No□
13	Have you ever been told by a medical professional that you are at risk of developing a blood clot?	Yes □ No□
14	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No□
15	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No□
16	Do you have or have you ever had breast cancer?	Yes □ No□
17	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes □ No□
18	Do you have cystic fibrosis, multiple sclerosis, lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No□
19	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No□
	- If yes, list them here:	
20	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No□
	- If yes, list them here:	

Do you have a preferred method of birth control that you would like to use?
□ A pill you take each day □ A patch that you change weekly □ Other (ring, injectable, implant, or IUD)

Internal use only □ verified DOB* with valid photo ID □ BP Reading ____/____
Pharmacist Name _____ Pharmacist Signature _____
Drug Prescribed _____ Rx# _____ -or- Patient Referred-circle reason(s)
Sig: _____ Pharmacy Phone_____ Address_____
Notes: _____ Date_____

…

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.

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

1. Evidence of HIV negative status as documented by an FDA- approved test, or rapid CLIA-waived point of care antigen/antibody fingerstick blood test, or by drawing blood (serum) and sending the specimen to a laboratory for an antigen/antibody test with results being received ~~taken~~ within 7 days prior to the initiation of PrEP. Neither oral swab testing nor patient report of negative status are acceptable for evidence.

2. Persons who meet eligibility requirements for PrEP per CDC guidelines in the following categories:

a. Sexually-Active Adults
- Anal or vaginal sex in the past 6 months
- Without acute or established HIV infection

~~b. 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~~
- HIV-positive sexual partner (especially if partner has an unknown or detectable viral load)
- Has tested positive for bacterial STI in the past 6 months
  - Gonorrhea, Chlamydia, and Syphilis for men who have sex with men (MSM) and transgender women (TGW) who have sex with men, including those who inject drugs
  - Gonorrhea and Syphilis for heterosexual women and men including persons who inject drugs

~~c. 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~~

~~d.~~b. Persons Who Inject Drugs (PWID)
- Adult person
- Without acute or established HIV infection
- Any injection of drugs not prescribed by a clinician in past 6 months

AND ~~at least one~~ any of the following:
- Any sharing of injection or drug preparation equipment in past 6 months
- Risk of sexual acquisition (see above)

~~e.~~c. Any patient who requests PrEP, even if no specific risk behaviors are elicited

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

- Patients with baseline HIV tests indicating existing HIV infection
- Recent flu-like symptoms in the past month as this may suggest acute ~~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)~~(fever, fatigue, myalgia, skin rash, headache, pharyngitis, cervical adenopathy, arthralgia, night sweats, diarrhea)
- Patients on medications contraindicated with PrEP therapy selected
- Patients with history of hypersensitivity reaction to PrEP therapy selected
- ~~CRCL < 60 ml/min~~

TABLE 1a – MEDICATION OPTIONS

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

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

Medication	Age/Weight	Frequency	Duration of Therapy	Notes
FTC/TDF(F/TDF) emtricitabine 200 mg/tenofovir disoproxil fumarate 300mg (Truvada® or generic)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <60 ml/min.
FTC/TAF (F/TAF) emtricitabine 200mg/tenofovir alafenamide 25mg (Descovy®)	≥35 kg	Once daily	Prescription issued for 30 days with no refills if baseline labs not completed; or up to 90 days if baseline labs completed. Refill quantity only until next scheduled lab follow up.	May take with or without food. Not recommended for CRCL <30 ml/min. Should only be used for at-risk cis-gender men and transgender women. Pharmacist must review drug/drug interaction considerations as per package insert ~~Table 5.~~
CAB Cabotegravir 600mg/3mL (Apretude®) extended-release injectable suspension for intramuscular (IM) use	>35kg	Month 1: 4-week optional oral lead in of daily cabotegravir 30mg (Vocabria®) tablet Month 2: 600mg (3mL) IM gluteal injection administered by healthcare professional on last day of oral therapy or within 3 days of last oral dose Month 3 (and every 2 months thereafter): 600mg (3ml) IM gluteal injection	Prescription issued for 1 injection at a time following the dosing and lab schedule	See package insert for instructions regarding planned or unplanned missed injections Drug-resistant HIV-1 variants have been identified with use of Apretude® (Black Box Warning)

		administered by healthcare professional		

~~**TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT**~~

Labs:

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

TABLE 2a – ROUTINE REQUIRED MONITORING OF INJECTABLE TREATMENT

Test	Frequency	CDC recommendations	Notes
HIV (Ag/Ab & HIV 1 RNA assay	Baseline + ~~Every 3 months~~ Prior to each injection + when stopping CAB	**Required**	If positive, refer
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + ~~At 3 mo if symptomatic. Every 6 monthsif asymptomatic~~ Every 4 months (starting with 3rd injection) for MSM & TGW Every 6 months (starting with 5th injection) for heterosexually-active persons When stopping CAB (only for MSM, TGW)	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

TABLE 2b-ROUTINE REQUIRED MONITORING OF ORAL TREATMENT

Test	**Frequency**	**CDC recommendations**	**Notes**
HIV Ag/Ab	Baseline + Every 3 months	**Required**	If positive, refer
HIV-1 RNA assay and assess for signs/symptoms of	Every 3 months + when stopping PrEP	**Required**	If positive, refer

acute HIV infection			
Three site STI screening (syphilis, gonorrhea, chlamydia)	Baseline + Every 3 months + when stopping PrEP ~~if symptomatic~~ for MSM & TGW Every 6 months ~~if asymptomatic~~ for heterosexually-active persons	Recommended	If positive – refer for care
Serum creatinine	Baseline + ~~at 3 months, and thereafter every 6 months~~ Every 6 mo. if age ≥50 or eCrCL <90 mL/min at PrEP initiation Every 12 mo. if continuing PrEP + When stopping PrEP	Recommended	If CrCL <60 mL/min, cannot use F/TDF If CrCL <30 mL/min, cannot use F/TAF If rapid decline in kidney function, consult nephrology
Weight, Lipid panel (if taking F/TAF)	Baseline, + Every 12 months	Recommended	
Hepatitis B screening	Baseline	Recommended	If positive – refer for care
Hepatitis C screening (for MSM, TGW, PWID only)	Baseline, + Every 12 months	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~~ infections.
- For injectable cabotegavir: the long drug "tail" of gradually declining drug levels when discontinuing CAB injections and the risk of developing a drug resistant strain of HIV during this time. To help patients safely discontinue CAB PrEP injections pharmacists should:
    - Re-educate patients about the tail and the risks during declining CAB levels
    - Asses ongoing risk/indications
    - If PrEP is indicated prescribe oral F/TDF or F/TAF beginning with 8 weeks after last injection
    - Educate about nPEP
    - Conduct HIV-1 RNA tests at each quarterly follow up visit after discontinuation of CAB injections and discuss the importance of keeping these follow up appointments

Documentation:

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

Referrals to primary care provider:

- If a patient tests positive for HIV infection, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care. A list of providers may be found at: ~~https://~~
- https://cdphe.colorado.gov/living-with-hiv

- If a patient tests positive for an STI, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and followup care. A list of providers may be found at: ~~https://www.colorado.gosv/pacific/cdphe/linkage-to-~~ ~~care~~https://cdphe.colorado.gov/living-with-hiv

- If a patient tests positive for Hepatitis B, the pharmacist will refer/direct the patient to a primary care provider and provide a list of providers and clinics in that region for confirmatory testing and follow up care.

- Urgent evaluation referral for symptoms or signs of acute renal injury or acute HIV infection.

- If a female patient becomes pregnant while on PrEP

- Usual care for any other issues, stress importance of routine primary care and health maintenance.

~~* 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~~

Non-Occupational Post-Exposure Prophylaxis (nPEP) Protocol

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

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

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

If the following criteria are met, antiretroviral agents in Table 3a~~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
- 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 3a~~1~~ may be prescribed. NPEP should strongly be considered after exposure in an individual who also meets the criteria for PrEP therapy (see Colorado StatewideProtocol for Pre-Exposure Prophylaxis of HIV).

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

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

Other Considerations:

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

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

TABLE 3a~~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	≥ 13 years	Once daily #28 no refills Twice daily #56 no refills	28 days	Dosing adjustments with renal dysfunction if CrCL <60 ml/min.
OR Dolutegravir 50mg		Once daily #28 no refills		Dolutegravir should not be used in pregnant women If contraindications to raltegravir or dolutegravir exist, or for other reasons the preferred regimen cannot be given, then "alternative regimens" per CDC guidelines should be referenced and used.

TABLE 4a~~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:

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

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

- Pharmacist is authorized to order the following labs for the patient OR can refer to another provider for ordering and accept lab work results.

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

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

Counseling (at minimum):

- Proper use of medication dosage, schedule and potential common and serious side effects (and how to mitigate)

- The importance of medication adherence with relation to efficacy of nPEP

- Signs/symptoms of acute HIV infection and recommended actions

- The patient should be instructed on correct and consistent use of HIV exposure precautions including condoms and not sharing injection equipment

- For women of reproductive potential with genital exposure to semen, emergency contraception should be discussed

- The necessity of follow up care with a primary care provider for usual care

- The importance and requirement of follow up testing for HIV, renal function, hepatic function, hepatitis B and C, and sexually transmitted diseases

- If appropriate, general discussion of pre-exposure prophylaxis at future time.

Documentation:

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

- The pharmacist will also follow all documentation rules in 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://cdphe.colorado.gov/living-with-hiv
- ~~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 followup care. A list of providers may be found at: https://cdphe.colorado.gov/living-with-hiv
- ~~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://cdphe.colorado.gov/living-with-hiv
- ~~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~~

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

[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

[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

Appendix E

Colorado State Board of Pharmacy Statewide Protocol

Statin Therapy

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

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

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

1. Hold a current license to practice pharmacy in Colorado

2. Be engaged in the practice of pharmacy

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

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

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

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

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

Records:

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

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

C.

Statin Therapy Protocol

Under this protocol, pharmacists may assess patients with or at high-risk for a CV event who are not currently on but in whom statin therapy is identified as a Class I recommendation according to AHA/ACC guidelines[1].

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

1. High-risk primary prevention
   a. 10-Year Atherosclerotic Cardiovascular Disease (ASCVD) Risk ≥20% using the American College of Cardiology risk calculator (found at http://tools.acc.org/ASCVD-Risk-Estimator-Plus/#!/calculate/estimate/) age 40-75
   -or-
   b. LDL ≥190 mg/dL tested using a fasting lipid panel, age 20-75

2. Primary prevention patients with diabetes mellitus
   a. Type 2 diabetes mellitus (DM) age 40-75 as determined by patient report, medical records, or prescription history

3. Secondary prevention
   a. Prior history of acute myocardial infarction, acute coronary syndrome, stable or unstable angina, coronary or arterial revascularization by coronary artery bypass graft (CABG) surgery and /or stenting, non-cardioembolic ischemic stroke, transient ischemic attack, aortic aneurysm, or peripheral artery disease ALL stemming from atherosclerotic origins
      - As confirmed by patient report, medical records, or prescription history

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

1. Patients who have a history of serious statin-associated side effects defined as a serum creatine kinase elevation >3 times the upper limit of normal, documented rhabdomyolysis from statin therapy, or hepatic transaminase elevations 3 times the upper limit of normal during prior treatment with statin therapy.

2. Patients who have active liver disease defined by medical history or by hepatic transaminases greater than 3 times the upper limit of normal.

3. Women who are pregnant or are of childbearing age and not using highly effective forms of contraception.

4. Patients with end stage renal disease (ESRD) or who are undergoing hemodialysis or peritoneal dialysis

5. Patients with severe hypertriglyceridemia (fasting triglycerides ≥ 1000 mg/dL)

TABLE 1 – MEDICATION OPTIONS

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

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

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

Patient Category	Medication and Dosage	Renal Adjustment	Frequency
High risk primary prevention* or secondary prevention	**Atorvastatin 40-80 mg**	No adjustment needed	Once daily
	Rosuvastatin 20-40 mg	CrCl < 30 ml/min/1.73m^2: 5-10 mg or consider atorvastatin 40-80mg	Once daily
Primary prevention patients with DM and not " high risk*"	**Atorvastatin 10-20 mg**	No adjustment needed	Once daily
	Fluvastatin 40 mg	No adjustment needed	Twice daily
	Fluvastatin XL 80 mg	No adjustment needed	Once daily
	Lovastatin 40-80 mg	CrCl <30 ml/min: 20 mg max dose	Once daily in evening
	Pitavastatin 1-4 mg	GFR 15-59 ml/min/1.73m^2: 1-2 mg	Once daily
	Pravastatin 40-80 mg	Severe impairment: 10 mg	Once daily in the evening
	Rosuvastatin 5-10 mg	No adjustment needed	Once daily
	Simvastatin 20-40 mg	Severe impairment: start at 5 mg (titrate as needed up to 20mg daily)	Once daily in the evening

* High risk primary prevention patients include: baseline LDL-C ≥190 mg/dL, diabetes age 40-75 years with LDL-C < 190 mg/dL and multiple ASCVD risk factors, or age 40-75 with LDL-C 70-189 mg/dL and 10-year ASCVD risk ≥20%.

TABLE 2 – ROUTINE REQUIRED MONITORING OF TREATMENT

Labs:

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

Counseling (at minimum):

- The importance of medication adherence with relation to efficacy of statin therapy and reduction in CV event risk, and what to do if patient misses a dose.
- Importance of therapeutic lifestyle changes in reducing lipids and CV risk.
- Proper use of medication, storage, dosage, schedule, and potential common and serious side effects (and how to mitigate).
- Signs/symptoms of myalgia and liver dysfunction, educate that side effects are not common
- Potential food and medication interactions (primarily with lovastatin and simvastatin)
- The necessity of follow up care with a primary care provider for usual care and lipid testing at least yearly.

Documentation:

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

- The pharmacist will also follow all documentation rules in Pharmacy Board Rule 17.

Referrals to primary care provider:

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

[1] Grundy SM, Stone NJ, Bailey AL, Beam C, Birtcher KK, Blumenthal RS, Braun LT, de Ferranti S, Faiella-Tommasino J, Forman DE, Goldberg R, Heidenreich PA, Hlatky MA, Jones DW, Lloyd-Jones D, Lopez-Pajares N, Ndumele CE, Orringer CE, Peralta CA, Saseen JJ, Smith SC Jr, Sperling L, Virani SS, Yeboah J. 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. J Am Coll Cardiol. 2019 Jun 25;73(24):e285-e350. doi: 10.1016/j.jacc.2018.11.003. Epub 2018 Nov 10. Erratum in: J Am Coll Cardiol. 2019 Jun 25;73(24):3237-3241. PMID: 30423393.
2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines | Journal of the American College of Cardiology (jacc.org)

DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

3 CCR 719-1

STATE BOARD OF PHARMACY RULES AND REGULATIONS

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

32.00.00 PROTECTIONS FOR PROVISION OF REPRODUCTIVE HEALTH CARE IN COLORADO

A. Basis. The basis for this rule is to implement the requirements of Executive Order D 2022 032, issued by Governor Jared Polis, sections 25-6-401 *et seq.*, 12-20-204, C.R.S., and 12-280-107(1), C.R.S.

B. Purpose. This rule is adopted to effectuate Executive Order D 2022 032, directing state agencies to protect access to reproductive health care in Colorado.

C. Definitions, for purposes of this Rule, are as follows:

1. "Applicant" means as defined in section 12-20-102(2), C.R.S.

2. "Assisting in the provision reproductive health care" means aiding, abetting or complicity in the provision of reproductive health care.

3. "Civil judgment" means a final court decision and order resulting from a civil lawsuit.

4. "Criminal judgment" means a guilty verdict, a plea of guilty, a plea of nolo contendere, *or* a deferred judgment or sentence.

5. "Licensee" means as defined in section 12-20-102(10), C.R.S.

6. "Provision of reproductive health care," includes but is not limited to, transportation for reproductive health care, referrals for reproductive health care and related services, funding or assisting with payment of reproductive health care, prescribing, shipping or dispensing medications for reproductive health care in accordance with state and federal law, all options and mental health counseling and treatment related to reproductive health care. The "provision of reproductive health care" also includes all treatment contemplated in the definition of section 25-6-402(4), C.R.S.

7. "Regulator" means as defined in section 12-20-102(14), C.R.S.

8. "Reproductive health care" means as defined in section 25-6-402(4), C.R.S.

D. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on the applicant or licensee's provision of or assistance in the provision of reproductive health care in this state or any other state or U.S. territory, so long as the care provided was consistent with generally accepted standards of practice as defined in Colorado law and did not otherwise violate Colorado law.

Commented [MD1]: Jack Teter – Planned Parenthood (7/22): Specify addressing laws of another state authorizing that state to bring civil, criminal or professional action against anyone providing or assisting in abortion care or anyone who is aiding or abetting in providing abortion care in another state.

May be worthwhile to consider providers who are in other states and who will travel to Colorado and relocate their practices and start to provide care here. What would we do around emergency licensure or temporary licensure for someone in Georgia that might lose their licensure in another state?

Allison Sorkin – UC Health (7/22): Providers who are compact providers and are licensed in another state where action is taken against their license in the primary state. Ensure license in Colorado is not revoked because of action in another state.

Commented [MD2]: Alison Sorkin – UC Health (7/22): If a complaint made to a Board regarding conduct that would not be criminal in Colorado and that there is not a concern that the standard of care has been met, that the Board would limit investigation so that it is not just investigating individuals' beliefs that are not against the law in this state. Policy? Non-jurisdictional?

Jack Teter – Planned Parenthood (7/22): Protections for providers – liability insurance, health care contracting, Medicaid, etc.

CA removed provider discretion to release information to law enforcement. CA protecting providers by removing obligation for providers. Requires court orders.

IVF – GA full fetal person went into effect. Need to transport embryos from other states to be thawed or disposed of. May be some cross state implications.

Samantha Toale, LPC (7/22): Is mandatory reporting going to be an issue? If a mandatory reporter is speaking to someone from another state where ...

Commented [MD3]: Laurie Lorrenzo, Pharmacist (7/22): Shipping and dispensing of medication

Federal law?

Commented [MD4]: Jack Teter, Planned Parenthood (7/22): Broaden to include all options counseling for patients who would be considering options may not fit under mental health counseling

Sharon Behl, LPC (7/22): counseling for prior medical care, during medical care, and post

May be family members of someone who sought abortion out of state who then seeks action against Colorado health care professionals ...

E. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on a civil or criminal judgment against the applicant or licensee arising from the provision of, or assistance in the provision of reproductive health care in this state or any other state or U.S. territory, so long as the care provided was consistent with generally accepted standards of practice and did not otherwise violate Colorado law.

F. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on a professional disciplinary action or any other sanction against the applicant's or licensee's professional licensure in this, or any other state or U.S. territory so long as the professional disciplinary action is based solely on the applicant or licensee's provision of, or assistance in the provision of, reproductive health care and the care provided was consistent with generally accepted standards of practice and did not otherwise violate Colorado law.

G. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's registration, certificate or license based solely on the licensee's own personal effort to seek or obtain reproductive health care for themselves. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on a civil or criminal judgment against the applicant or licensee arising from the individual's own personal receipt of reproductive health care in this state or any other state or U.S. territory.

33.00.00 PROTECTING COLORADO'S WORKFORCE AND EXPANDING LICENSING OPPORTUNITIES

A. Basis. The basis for this rule is to implement the requirements of Executive Order D 2022 034, issued by Governor Jared Polis, sections 25-6-401 *et seq.*, 12-20-204, C.R.S., and 12-280-107(1), C.R.S.

B. Purpose. This rule is adopted to effectuate Executive Order D 2022 034, directing the Board to promulgate and issue rules to ensure that no person shall be subject to disciplinary action against a professional license or disqualified from professional licensure for any civil or criminal judgment, discipline, or other sanction threatened or imposed under the laws of another state regarding consumption, possession, cultivation or processing of marijuana so long as the actions are lawful and consistent with professional conduct and standards of care within the State of Colorado.

C. Definitions, for purposes of this Rule, are as follows:

1. "Applicant" means as defined in section 12-20-102(2), C.R.S.

2. "Civil judgment" means a final court decision and order resulting from a civil lawsuit.

3. "Criminal judgment" means a guilty verdict, a plea of guilty, a plea of nolo contendere, *or* a deferred judgment or sentence.

4. "Licensee" means as defined in section 12-20-102(10), C.R.S.

5. "Regulator" means as defined in section 12-20-102(14), C.R.S.

D. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on a civil or criminal judgment against the applicant or licensee regarding the consumption, possession, cultivation, or processing of marijuana so long as the actions are lawful and consistent with professional conduct and standards of care within Colorado and did not otherwise violate Colorado law.

Commented [MD5]: Do any of these need to be defined?

E. The regulator shall not deny licensure to an applicant or impose disciplinary action against an individual's license based solely on a professional disciplinary action against the applicant's or licensee's professional licensure in this, or any other state or US territory so long as the professional disciplinary action is based solely on the applicant's or licensee's consumption, possession, cultivation, or processing of marijuana and did not otherwise violate Colorado law.

…

DEPARTMENT OF REGULATORY AGENCIES

State Board of Pharmacy

3 CCR 719-1

STATE BOARD OF PHARMACY RULES AND REGULATIONS

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

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

A. Basis: The basis for this rule is to implement the requirements of section 12-30-112, C.R.S., in consultation with the Commissioner of Insurance and the State Board of Health.

B. Purpose: The purpose of these rules and regulations is to establish the requirements for health care providers to provide disclosures to consumers about the potential effects of receiving emergency or non-emergency services from an out-of-network provider as required by section 12-30-112, C.R.S.

C. Definitions, for purposes of this Rule, are as follows:

1. "Publicly available" means, for the purposes of this regulation, searchable on the health care provider's public website, displayed in a manner that is easily accessible, without barriers, and that ensures that the information is accessible to the general public, including that it is findable through public search engines. The health care provider's public website must be accessible free of charge, without having to establish a user account, password, or other credentials, accept any terms or conditions, and without having to submit any personal identifying information.

D. Disclosure requirements.

1. An out of network provider may balance bill a covered person for post-stabilization services in accordance with section 10-16-704, C.R.S., and covered nonemergency services in an in-network facility that are not ancillary services if the provider meets the requirements set forth in section 12-30-112(3.5), C.R.S. If a consumer has incurred a claim for emergency or nonemergency health care services from an out-of-network provider, the health care provider shall provide the disclosures contained in Appendix E in compliance with section 12-30-112(3.5), C.R.S.

2. The health care provider shall provide the disclosure contained in Appendix E as set forth in section 12-30-112(3.5), C.R.S. :

E. Noncompliance with this Rule may result in the imposition of any of discipline made available by section 12-280-126(1)(c), C.R.S.

…

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Commented [MD1]: What other definitions should be included?

Commented [MD2]: Mirrored DOI's definition

APPENDIX E

Your Rights and Protections Against Surprise Medical Bills

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

What is "balance billing" (sometimes called "surprise billing")?

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

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

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

You're protected from balance billing for:

Emergency services

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

[Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed language as appropriate]

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

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

If you get other types of services at these in-network facilities, out-of-network providers can't balance bill you, unless you give written consent and give up your protections.

You're never required to give up your protections from balance billing. You also aren't required to get out-of-network care. You can choose a provider or facility in your plan's network.

Commented [MD3]: These are linked in the Federal Model Disclosure. Should these terms be defined in rule?

Commented [MD4]: What language should be added here? Reference to the statute – 12-30-112?

DOI has this:

If you believe you've been wrongly billed, please contact the Division of Insurance at the number on your ID card, 303-894-7490, 1-800-930-3745, or DORA_Insurance@state.co.us.

Visit the CMS No Surprises Act website for more information about your rights under federal law.
Visit DOI Out-of-Network website for more information about your rights under Colorado state law.

[Insert plain language summary of any applicable state balance billing laws or requirements OR state-developed language regarding applicable state law requirements as appropriate]

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

- You're only responsible for paying your share of the cost (like the copayments, coinsurance, and deductible that you would pay if the provider or facility was in-network). Your health plan will pay any additional costs to out-of-network providers and facilities directly.

- Generally, your health plan must:

  - Cover emergency services without requiring you to get approval for services in advance (also known as "prior authorization").

  - Cover emergency services by out-of-network providers.

  - Base what you owe the provider or facility (cost-sharing) on what it would pay an in-network provider or facility and show that amount in your explanation of benefits.

  - Count any amount you pay for emergency services or out-of-network services toward your in-network deductible and out-of-pocket limit.

If you think you've been wrongly billed, contact [Insert contact information for entity responsible for enforcing the federal and/or state balance or surprise billing protection laws. The federal phone number for information and complaints is: 1-800-985-3059].

Visit [Insert website describing federal protections, such as

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

[If applicable, insert: Visit [website] for more information about your rights under [state laws].]

Commented [MD5]: What should be added here?

Commented [MD6]: What should be added here?

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.