Basis and Purpose: The purpose of the addition of Board Rule 17.00.00 is to implement SB 16-135 which allows qualified Colorado-licensed pharmacists to perform evidence-based healthcare services pursuant to either: (1) an agreement and a protocol with Colorado-licensed physicians and Colorado-licensed advanced practice registered nurses; or (2) a statewide protocol.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, 12-42.5-603 and 24-4-103, C.R.S.

17.00.00 COLLABORATIVE PHARMACY PRACTICE.

17.00.10 Definitions.

a. "Collaborative pharmacy practice agreement" means a written and signed agreement entered into voluntarily between one or more Colorado-licensed pharmacists and one or more Colorado-licensed prescribers, 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 prescriber or prescribers. Either party may withdraw from an agreement at any time.

b. "Collaborative pharmacy practice agreement" may also mean a statewide drug therapy 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.

c. "Evidence-based healthcare service" means a healthcare service provided by a Colorado-licensed pharmacist pursuant to a statewide protocol or an agreement and protocol 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. For the purpose of this Board Rule 17.00.00, evidence-based healthcare service does not mean "Drug therapy management" as defined and governed under Board Rule 6.00.00.

d. "Prescriber", for the purpose of this Board Rule 17.00.00, means a physician who is actively licensed by the Colorado Medical Board or an advanced practice registered nurse who is actively 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 physicians or advanced practice registered nurses 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.

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 Service 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;

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 the generally accepted standard of care in all applicable professions; and

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

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

17.00.70 Evidence-Based Healthcare Service Pursuant to 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 name(s);

2. Participating prescriber name(s);

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

4. Protocols to be employed;

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

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

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

8. An effective date of the agreement, and signatures of both the participating prescriber or prescribers and pharmacist or pharmacists; 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:

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;

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 the 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; and

6. An effective date of the protocol, and signatures of the authorized prescriber or prescribers.

17.01.00 Record-Keeping Requirements.

a. Pharmacists engaging in evidence-based healthcare services shall maintain, 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 training as specified in either the statewide protocol or protocol entered into with a prescriber or prescribers; and

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

c. 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 evidence-based healthcare services shall be retained for a minimum of three (3) 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 24 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 any rules promulgated pursuant to the act and other federal and state laws and rules. Specifically, pharmacists can only release patient information to:**

1. **The patient or the patient's agent;**

2. **A practitioner or another pharmacist if, in the pharmacist's professional judgment, the release is necessary to protect the patient's health and well-being;**

3. **The Board or to a person or another state or federal agency authorized by law to receive the confidential record;**

4. **A person employed by a state agency that licenses a practitioner, if the person is performing the person's official duties; and/or**

5. **An insurance carrier or other third party payer authorized by the patient to receive the information.**

Basis and Purpose: The purpose of the proposed repeal of Board Rule 18.00.00 is to achieve consistency within the Division of Professions and Occupations ("Division") in that the duties of the Pharmacy Peer Health Assistance Program ("Program") are governed under a single, shared business contract between the affected boards within the Division and the entity administering the Program. The purpose is to further eliminate unnecessary regulation.

Authority for Promulgation of Rules: Sections 12-42.5-101, 12-42.5-105, and 24-4-103, C.R.S.

~~**18.00.00 PHARMACY PEER HEALTH ASSISTANCE PROGRAM.**~~

~~**18.00.10 Definitions.**~~

~~**a. "Board" means the Colorado State Board of Pharmacy.**~~

~~**b. "Board-ordered" means a Licensee or Program Participant who has been ordered by the Board to enter or complete a Diversion Program Contract pursuant to:**~~

~~**1) a Stipulation and Final Agency Order,**~~

~~**2) a Final Agency Order issued subsequent to an Initial Decision entered by an Administrative Law Judge following a disciplinary hearing pursuant to CRS 24-4-105, or**~~

~~**3) a Board order entered pursuant to CRS 12-42.5-204(3) directing a Licensee to be evaluated and/or participate in the Diversion Program.**~~

~~**c. "Licensee" means a person who is a pharmacist or pharmacist intern, who possess an active license issued by the Board, or has applied for licensure and paid all required fees.**~~

~~**d. "PHAO" means a Peer Health Assistance Organization under contract with the Board which provides a formal, structured program that meets the requirements specified in Title 12, Article 42.5, Part2 of the Colorado Revised Statutes. Such program shall be administered by appropriate professionals for the purpose of assisting Licensees and Program Participants experiencing impaired practice to obtain evaluation, treatment, short-term counseling, monitoring of progress, and ongoing support for the purpose of arresting and treating the Licensee's or Program Participant's psychiatric, psychological, or emotional conditions or excessive alcohol or drug use or addiction.**~~

~~**e. "PHAO Contract" means the contract between a Peer Health Assistance Organization ("PHAO") and the Department of Regulatory Agencies, as awarded in accordance with State law, for operation of the Pharmacy Peer Health Assistance Program.**~~

~~**f. "Pharmacy Peer Health Assistance Program" means, and refers to, the Pharmacy Peer Health Assistance Diversion Program under 12-42.5-201, et seq., C.R.S.**~~

~~**g. "Program" means the treatment program and all associated services provided by the PHAO to the Program participant.**~~

h. "Program contract" means a contract between the PHAO and a Program participant to detail a treatment/recovery plan or other kind of support services plan as determined necessary by the PHAO, and to provide other program services as outlined in the contract.

i. "Program participant" means a licensee who is enrolled in the Program and has a Program contract with the PHAO.

j. "Program participants with active cases" means those licensees who are currently Board-ordered to receive an evaluation, treatment referral and/or monitoring with the PHAO, and those licensees whose cases have been referred for discipline or a confidential agreement.

18.01.00 Peer Health Assistance Organizations (PHAO).

18.01.10 General Responsibilities.

Each PHAO which enters a PHAO Contract to provide Program services for the Board shall be responsible for the following:

a. Performing assessments and evaluations of licensees who self-refer or are referred to the PHAO by the Board, and such additional evaluations and assessments as are deemed necessary by the PHAO or requested by the Board.

b. Entering into a Program contract with licensees admitted into the program ("Program participants").

c. Informing each Program Participant of his/her rights and responsibilities under the Program contract and the possible consequences of non-compliance.

d. Corresponding with Program participants regarding Board actions relevant to the Program participants.

e. Notifying a Program participant and the Board of instances of noncompliance by the Program Participant or of the termination of the Program participant from the program.

f. Destruction of all material maintained by the PHAO three years after a Program participant's successful completion of or termination from the program.

g. Other duties as set forth in the PHAO Contract.

18.01.11 Quarterly Reports to the Board by PHAO's.

The PHAO shall submit compliance reports for the previous quarter during the months of April, July, October and January for participants ordered to participate in the Program. Compliance reports may include summaries of, but are not be limited to:

a. Records of attendance by Program participants at all prescribed therapeutic activities including, but not limited to, counseling sessions, group meetings, and drug urine screens.

b. Records of attendance and performance from the Program participants' supervisors/employers.

~~c. Records of monitored Antabuse or other relevant prescribed medications/agents.~~

~~d. Reports by treatment provider(s).~~

~~e. Evaluations and assessments.~~

~~f. Self-status reports.~~

~~g. Reports as required by the Program participants' Program contracts.~~

~~h. Other details as required in the PHAO Contract.~~

~~18.01.12 Confidentiality.~~

~~a. Any compliance report submitted by a PHAO to the Board regarding the progress of a Program Participant in the Program shall be reported to the Board by case number only, except as specified in paragraphs b through d below.~~

~~b. Whenever any Program participant tests positive for alcohol or drugs, or otherwise chronically and/or substantially fails to comply with his/her Program contract, the PHAO shall report the Program participant by name to the Board.~~

~~c. When the PHAO reports a participant's failure to comply with the Program contract, the Program participant's treatment records and reports will no longer be kept confidential from the Board. Such reports and records shall remain confidential and be subject to protection from further disclosure pursuant to CRS 24-72-204(3)(a)(I).~~

~~d. The PHAO shall maintain and keep confidential a Program participant's Program records for three years after completion of or termination from the program and then destroy them.~~

~~18.03.00 Program - Eligibility, Participation, Program Completion or Termination of Individual Licensees.~~

~~18.03.10 Program Participation.~~

~~a. Voluntary Participation. To be eligible for voluntary participation in the Program, a licensee shall:~~

~~1) Be a pharmacist or intern who possesses a currently active license in this state.~~

~~2) Have a psychiatric, psychological or emotional condition or abuse alcohol and/or drugs in a manner which may affect the licensee's ability to practice with reasonable skill and safety.~~

~~3) Voluntarily request admission into the program.~~

~~4) Agree to undergo reasonable evaluation and examination necessary for the determination of need and ability to participate in the program.~~

~~5) Bear the cost of the program.~~

6) Cooperate by providing such evaluation and treatment information, disclosure authorizations and releases of liability as may be requested by the PHAO.

7) Sign a written Program contract with the PHAO including a treatment/recovery plan in which the Licensee agrees to comply with all elements of the Program.

b. Mandatory Participation. A licensee is eligible for Program participation and services if the licensee:

1) Enters into a Stipulation and Final Agency Order wherein the Licensee agrees to participate in the Program as a term of disciplinary probation; or

2) Is ordered into the Program for treatment pursuant to a Final Agency Order following a disciplinary hearing; or

3) Is Board-ordered to enter into the Program for treatment pursuant to CRS 12-42.5-204(3).

4) Has a psychiatric, psychological or emotional condition or abuses alcohol and/or drugs in a manner which may affect the licensee's ability to practice with reasonable skill and safety.

5) Bears the cost of the program.

6) Cooperates by providing such evaluation and treatment information, disclosure authorizations and releases of liability as may be requested by the PHAO.

7) Signs a written Program contract with the PHAO including a treatment/recovery plan in which the licensee agrees to comply with all elements of the Program.

c. In the event that a previously voluntary Program participant is subsequently Board-ordered to participate in and/or complete the Program, the Program participant shall enter into a new Program contract with the PHAO in which it is indicated that the Program participant's participation in the Program was Board-ordered.

18.03.11 Admission Procedures.

a. Each Licensee requesting admission into the Program shall submit an application to the PHAO.

b. Each Program participant will be assigned a case number by the PHAO for the purpose of confidential identification during the Program participant's participation in the program in a manner consistent with Rule 18.01.13, below.

c. The Program participant shall enter into a Program contract with the PHAO signed by Program participant and an authorized representative of the PHAO. The Program contract is to be kept in the confidential files of the PHAO with a copy provided to the Program participant and any other lawfully authorized parties.

d. The term of any Program contract between the Program participant and the PHAO shall be determined by the PHAO unless superseded by Board order. The term of the Program contract may be extended and/or retroactive credit may be given at the discretion of the PHAO unless superseded by Board order.

e. In any case where the Program participant has been Board-ordered into the Program, the PHAO shall submit a copy of the Program contract to the Board for inclusion in the Board's files.

18.03.12 Reports to the Board for Non-Compliance.

Notwithstanding any other provision of these Rules, if the PHAO determines that any applicant, licensee, or Program participant is unable to practice with reasonable skill and safety, the applicant, licensee, or Program participant shall be reported by name with supporting written documentation to the Board by the next business day.

18.03.13 Successful Discharge of a Program Participant from the Program.

A Program participant shall be considered to have completed the Program when the Program participant has complied with all of the terms and conditions of the Program contract, has completed the contractual treatment program, and the PHAO has determined that the Program participant can safely practice pharmacy without further treatment or monitoring.

18.03.14 Termination of a Program Participant from the Program.

A Program participant may be terminated from his/her Program contract with the PHAO for failure to comply with the treatment/recovery plan or any terms of the Program contract with the PHAO.