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.]

6.00.00 PHARMACEUTICAL CARE, DRUG THERAPY MANAGEMENT AND PRACTICE BY PROTOCOL. (REPEALED)

~~6.00.10 Definitions.~~

~~a. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health care professionals to attain the desired outcome. This function includes efforts to prevent, detect, and resolve medication related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority.~~

~~b. For the purpose of this Board Rule 6.00.00, a "prescriber" 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.~~

~~c. Drug therapy management means the review and evaluation of drug therapy regimens for patients undertaken by a pharmacist in order to provide drug therapy, monitor progress, and modify drug therapy. Drug therapy management may only be undertaken pursuant to an initial diagnosis made by a prescriber, a valid order for the therapy, and a written agreement, which delineates proper protocols, to be used and the type of interaction that must occur between the pharmacist and the prescriber. 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.~~

~~d. Drug therapy management may include:~~

~~1. Collecting and reviewing patient drug histories;~~

~~2. Obtaining and checking vital signs;~~

~~3. Ordering and evaluating the results of laboratory tests directly, related to management of the drug therapy when performed in compliance with the protocol ordered by the prescriber;~~

~~4. Modifying drug therapy, when appropriate, in compliance with the protocol ordered by the prescriber; and~~

5. Implementing the drug therapy plan agreed upon between the prescriber and the pharmacist, using protocols and managing the therapy according to those protocols.

e. Protocol means a specific written plan for a course of medical treatment containing a written set of specific directions created by the prescriber, groups of prescribers, hospital medical committee, or pharmacy and therapeutics committee.

1. Protocols must describe the nature and scope of drug therapy management appropriate for certain conditions or diagnoses, and include specific directions for the drug to be used, the specified dosage regimen, dosage forms or route of administration which are authorized. Protocols must include clear criteria and specific directions pharmacists are to follow when implementing and monitoring drug therapy. If the protocol includes ordering and evaluating laboratory tests, the protocol must provide precise instruction as to what tests are to be ordered, the criteria for ordering the tests, how the tests are to be interpreted, and what action the pharmacist is to take dependent upon the test results. If the protocol includes modifying drug therapy, the protocol must provide precise instruction as to the criteria dictating a change, and exactly how the therapy is to be changed.

2. Protocols without specific directions regarding patient treatment or those that are nonspecific, vague, or rely on discretion without definition, are insufficient and may not be used in drug therapy management by the prescriber or the pharmacist.

3. Protocols must also include specific instructions for responding to acute allergic or other adverse reactions. The protocols shall be signed and dated by the authorizing prescriber or chairperson of the authorizing group or committee.

4. 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. Through the use of such protocols, drug therapy management must provide care that meets the standard of care in all applicable professions.

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

f. Agreement means a written agreement between a Colorado licensed pharmacist and a Colorado licensed prescriber, or a group of Colorado licensed pharmacists and a group of Colorado licensed prescribers that sets forth the specific information required to assure the competent practice of pharmacy in an integrated health care fashion. Either party may withdraw from the agreement at any time.

6.00.20 Drug therapy management requirements for all practice settings.

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

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

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

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

e. Pharmacists may perform by protocol all aspects of drug therapy management referenced in 6.00.10 c and d, provided the protocol complies with 6.00.10e, and the pharmacists performing these functions are qualified as set forth in section 6.00.30 and are working pursuant to a written agreement with an appropriately qualified prescriber.

f. Filing requirements.

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

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

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

6.00.30 Pharmacist Qualifications.

Any pharmacist engaged in drug therapy management shall meet the following qualifications:

a. Have and maintain an unrestricted license in good standing to practice pharmacy in Colorado; and

b. Meet one of the following qualifications:

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

2. Proof of completion of one (1) year of practice experience in pharmacotherapy, and 40 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 in each area of practice, and 40 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 40 hours of ACPE approved continuing education regarding clinical practice and 40 hours of onsite 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 Specialties, current certification from the National Institute for Standards in Pharmacist Credentialing, or current certification from the Commission for Certification in Geriatric Pharmacy. Such credentials must be in the area of pharmacy practice undertaken in the drug therapy management; or

6. In an inpatient or group model integrated closed HMO setting, all of the following criteria shall be met in order to practice drug therapy management:

a. Forty (40) hours of onsite 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 of each area of practice in which the pharmacist is choosing to practice shall be maintained on site.

c. Licensed Colorado pharmacists practicing 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 to 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.

6.00.40 Drug Therapy Management in Inpatient and Group Model Integrated Closed HMO Settings.

a. Pharmacists engaging in drug therapy management in inpatient and group model integrated closed HMO settings must conduct activities pursuant to a valid order and must follow the protocols set forth by the hospital medical committee, or pharmacy and therapeutics committee. They must record all of the items required in subsection c. below for each patient, or the hospital may create a general authorization plan, identifying where such information will be located, and how it will be accessed throughout the facility by participating pharmacists and prescribers. The general authorization plan serves as the pharmacist/prescriber agreement in these settings. The general authorization plan must identify which prescribers and pharmacists are authorized and have agreed to participate in the facility to engage in drug therapy management. The hospital medical committee or pharmacy & therapeutics committee serves as the authorizing agent for the organization's medical staff, identifying which prescriber groups are authorized to participate, and may restrict authorization for certain protocols to specific prescriber groups or specialties. A pharmacist engaging in drug therapy management must read,

sign and date the plan and the pertinent protocols that he/she agrees to use in the cases undertaken.

b. The pharmacist manager shall ensure that the general authorization plans for drug therapy management are on file in the prescription drug outlet. Changes to the plan must be made as they occur, including the identification of persons participating. Protocols shall be onsite where the drug therapy management takes place and revised as medically necessary.

c. Prior to initiation of drug therapy management, the pharmacist must review the following information:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from physician);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Emergency contact number.

d. Records of all activity by the pharmacist shall be documented in the patient's chart prior to administration.

e. Pharmacists engaging in drug therapy management shall not delegate drug therapy management activities to any other staff.

6.00.50 Drug Therapy Management in other settings.

a. Every pharmacist or group of pharmacists engaged in drug therapy management in an outpatient setting must have a valid order from the patient's prescriber for each specific patient for such therapy, and must operate according to a written agreement and protocol referenced in section 6.00.10.

b. Written agreements shall contain the following information:

1. Participating pharmacist name(s);

2. Participating prescriber name(s);

3. Diagnoses relevant to the drug therapy to be managed and other patient conditions relevant to maintenance of the patient's health during drug therapy management;

4. Protocols to be employed;

5. Functions and activities the pharmacist will perform, and restrictions or limitations on the pharmacist's management;

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

7. Manner in which pharmacist's drug therapy management will be monitored by the prescriber, including method and frequency;

8. A specified time, not to exceed 24 hours, within which the pharmacist must notify the prescriber of any modifications of drug therapy;

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

10. An effective date of the agreement, and signatures of both parties.

11. A provision addressing how drug therapy management will be handled when the patient has more than one prescriber involved in evaluating or treating the medical condition which is the subject of the agreement. All prescribers who are actively involved in the management of the relevant conditions shall be parties to the agreement.

c. Prior to implementation of drug therapy management, pharmacists shall secure the following information:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from prescriber);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Emergency contact number.

d. Pharmacists engaging in drug therapy management shall not delegate drug therapy management responsibilities to any other staff.

6.00.60 Recordkeeping.

a. Pharmacists must document all actions taken in drug therapy management, including but not limited to any data required by the protocol. Records of each patient visit must be transmitted to the prescriber in the manner specified in the agreement. Records must indicate when and how the record was transmitted to the prescriber.

b. Pharmacists must keep patient records that include:

1. Patient's name, gender, date of birth, height, and weight;

2. Patient diagnosis or diagnoses (from physician);

3. Medication history;

4. Prior lab values;

5. Patient vital signs;

6. Patient known allergies;

7. Date and time the service was rendered;

8. Type of service rendered;

9. Results of interviews with the patient and any diagnostic tests or other pertinent information about the patient's disease;

10. When and how the record was transmitted to the prescriber; and

11. Emergency contact number.

6.00.70 Retention of Records.

a. All records of drug therapy management shall be retained for a minimum of seven years from the last date of drug therapy management, or seven years from the patient's 18th birthday, whichever is later. Such records shall be available for inspection by the patient, the prescriber, the Board, 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.

6.00.90 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.~~

~~6.01.10 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 drug therapy management.~~

~~6.01.20 Board Review.~~

~~a. Board staff will review compliance with this rule and report to the Board regarding complaints and other relevant data associated with the rule every three years.~~

17.00.00 COLLABORATIVE PHARMACY PRACTICE.

17.00.10 Definitions.

a. "Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services by a pharmacist intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process. In addition to the preparation, dispensing, and distribution of medications, "pharmaceutical care" may include assessment and evaluation of the patient's medication--related needs and development and communication of a therapeutic plan with defined outcomes in consultation with the patient and the patient's other health care professionals to attain the desired outcome~~s~~. This function includes efforts to prevent, detect, and resolve medication--related problems for individual patients. "Pharmaceutical care" does not include prescriptive authority; except that a pharmacist may prescribe only over-the-counter medications to a recipient under the "Colorado Medical Assistance Act" as authorized pursuant to section 25.5-5-322, C.R.S., or pursuant to a collaborative pharmacy practice agreement as defined in section 12-280-601(1)(b), C.R.S. ~~Statewide Protocol~~.

~~a.~~b. "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,~~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 physician or advanced practice nurse with prescriptive authority.~~prescriber or prescribers.~~ 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 nurs~~s~~e~~prescriber~~, 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 ~~prescriber~~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.

c~~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.

d~~c~~. "Evidence-based healthcare service" means a healthcare service provided by a Colorado-licensed pharmacist pursuant to a collaborative practice agreement ~~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.~~

e~~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.

f~~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;

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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.

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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;

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

G. Required patient counseling considerations for approved medications; and

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

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

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

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

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

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) ~~name(s)~~;

2. Participating prescriber(s) ~~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, 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:

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 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, 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 agreed upon in relation to drug therapy management;

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

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 treatment protocol. 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.

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. 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.

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)(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.

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 ~~Pharmacists engaging in evidence-based healthcare services~~ 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 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.

b~~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 collaborative pharmacy agreements ~~All records of evidence-based healthcare services~~ 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 ~~any rules promulgated pursuant to the act and other federal and state laws and rules. Specifically, pharmacists can only release patient information to:~~ the HITECH Act of 2009, and other federal and state laws and rules.

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

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~~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.~~

17.04.00 Participation Not Mandatory

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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.