WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: Medicine TITLE-SERIES: 11-08

RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No

RULE NAME: Collaborative Pharmacy Practice

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: W. Va. Code § 30-5-7(c)

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

W. Va. Code § 30-5-7(c)

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/29/2022

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/29/2021

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

The Board published notice of the proposed amendments and comment period on the Board of Medicine website with a link to the proposed rule and sent email notification to licensees and registrants of the Board regarding notice of the proposed amendments and comment period with a link to the proposed rule. Additionally, the Board notified the West Virginia State Medical Association.

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule is jointly agreed upon and proposed by the Boards of Pharmacy, Medicine, and Osteopathic Medicine for legislative approval pertaining to a pharmacists scope of practice pursuant to collaborative pharmacy practice and collaborative pharmacy practice agreements, content of collaborative pharmacy agreements, responsibilities of a pharmacist and physician with respect to collaborative pharmacy agreements, the content, process and fee for filing collaborative pharmacy practice notifications, and the termination of collaborative pharmacy practice agreements by the parties or the boards. It also sets forth relevant disciplinary processes for pharmacists and physicians related to collaborative pharmacy practice.

Section 1 revises the scope of the rule, updates the reference to the joint rulemaking authority conferred upon the boards of Pharmacy, Medicine and Osteopathic Medicine and incorporates a Sunset provision subsection.

Section 2 eliminates definitions which related to the former collaborative pharmacy practice pilot program, updates some definitions based upon House Bill 4324, and adds additional relevant definitions, including definitions for boards, collaborating pharmacist, collaborating physician, controlled substance, pharmacist case, practice notification, and website.

Section 3 establishes the requirements for collaborative pharmacy practice, including a collaborative pharmacy practice agreement developed between collaborating pharmacists and physicians at the practice level and the submission of a complete and valid practice notification to the boards. This section establishes eligibility for participation in collaborative pharmacy practice agreements, and the role of the Board of Pharmacy in verifying pharmacist eligibility. This section sets forth the required contents and filing process for practice notifications, which, if complete, are effective upon filing with the Board of Pharmacy and details how practice notification information will be shared by the boards. This section requires the boards to maintain a current list of all practice notifications for collaborative pharmacy practice.

Section 4 details the purpose and required content of collaborative pharmacy practice agreements, which are developed and implemented at the practice level and maintained by collaborating pharmacists at their place of practice. The amendments to this section conform the practice protocols to the changes implemented by House Bill 4324, and require the protocols to be filed in the patient medical record.

Section 5 is amended to clarify that collaborating practitioners may terminate a collaborative pharmacy practice agreement voluntarily, and that it automatically terminates if the collaborating pharmacist or physician is no longer eligible to collaborate. It provides a process for notifying the Board of Pharmacy of the termination of a collaborative pharmacy agreement. This section clarifies that patients may revoke consent to have drug therapy management pursuant to collaborative pharmacy practice at any time.

Section 6 is amended to ensure that an employment arrangement does not interfere with a pharmacists or physicians sound clinical judgment or obligation to patients.

Section 7 is amended to clarify disciplinary procedures.

These amendments were approved by the West Virginia Board of Pharmacy, the West Virginia Board of Osteopathic Medicine and the West Virginia Board of Medicine.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

During the 2022 legislative session, the West Virginia Legislature passed House Bill 4324, which modified W. Va. Code §§ 30-5-4 and 30-5-19 to modernize collaborative pharmacy practice and to streamline procedures relating to the registration of collaboration with the boards of Pharmacy, Medicine and Osteopathic Medicine. The proposed amended rule aligns with the requirements of House Bill 4324.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

None

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

None

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

None

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year

	2022 Increase/Decrease (use "-")	2023 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues			

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

N/A

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Mark A Spangler -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 11
LEGISLATIVE RULE
WEST VIRGINIA BOARD OF MEDICINE

SERIES 8
COLLABORATIVE PHARMACY PRACTICE

§11-8-1. General.

1.1. Scope. -- This rule is jointly agreed upon and proposed by the Boards of Pharmacy, Medicine, and Osteopathic Medicine for legislative approval pertaining to a pharmacist's scope of practice pursuant to collaborative pharmacy practice and collaborative pharmacy practice agreements, content of collaborative pharmacy agreements, responsibilities of a pharmacist and physician with respect to collaborative pharmacy agreements, the content, process and fee for filing collaborative pharmacy practice notifications, and the termination of collaborative pharmacy practice agreements by the parties or the boards.

1.2. Authority. -- W. Va. Code §30-5-~~28~~7(c).

1.3. Filing date. -- ~~April 4, 2008~~.

1.4. Effective date. -- ~~July 1, 2008~~.

1.5. Sunset Provision – This rule shall terminate and have no further force or effect upon August 1, 2028.

§11-8-2. Definitions.

~~2.1.~~ For purposes of this rule, the following definitions apply:

~~a. "*CLIA*" means the Clinical Laboratory Improvement Amendments, a program operated through the Center for Medicare and Medicaid Services.~~

2.1. "Boards" means the West Virginia Board of Pharmacy, the West Virginia Board of Medicine, and the West Virginia Board of Osteopathic Medicine.

2.2. "Collaborating pharmacist" means a pharmacist licensed in West Virginia who has been verified by the Board of Pharmacy to engage in collaborative pharmacy practice:

With one or more collaborating physicians:

Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

For which a complete and valid practice notification is filed with the boards.

2.3. "Collaborating physician" means a doctor of medicine or osteopathic medicine fully and actively licensed to practice clinical medicine, without restriction, in West Virginia by the Board of Medicine or the Board of Osteopathic Medicine who collaborates with pharmacists:

Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

For which a complete and valid practice notification is filed with the boards.

A physician in training may also collaborate with pharmacists pursuant to an active collaborative pharmacy agreement if the trainee's supervising physician or medical department chair executes the collaborative pharmacy practice agreement and the physician in training collaborates under the supervision of the physician who executed the agreement.

~~b.~~ 2.4. "Collaborative pharmacy practice" is that practice of pharmac~~y~~ist care where one or more pharmacists have jointly agreed, on a voluntary basis, to work in conjunction with one or more physicians under written protocol where the pharmacist or pharmacists may perform certain patient care functions authorized by the physician or physicians under certain specified conditions and limitations.

~~c.~~ 2.5. "Collaborative pharmacy practice agreement" is a written and signed agreement, which is a physician directed approach, that is entered into between an individual physician or physician group, or for a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient. ~~"*Collaborative pharmacy practice agreement*" is a written and signed agreement between a pharmacist, a physician, and the individual patient or the patient's authorized representative who has granted his or her informed consent, that provides for collaborative pharmacy practice for the purpose of drug therapy management of a patient, which has been approved by the Board of Pharmacy, the Board of Medicine in the case of an allopathic physician or the West Virginia Board of Osteopathy in the case of an osteopathic physician.~~

~~d.~~ 2.6. "Collaborative pharmacy practice protocol" is the detailed written portion of the collaborative pharmacy practice agreement pursuant to which the authorized pharmacist will base drug therapy management decisions for patients.

2.7. "Controlled substances" means drugs that are classified by federal or state law in Schedules I, II, III, IV or V, as defined in W. Va. Code Chapter 60A, Article 2.

~~e. *"Community practice protocol"* means a written, executed agreement entered into voluntarily between an authorized pharmacist and a physician establishing drug therapy management for one or more of the pharmacist's and physician's patients residing in a community setting. A community practice protocol shall comply with the requirements of paragraph 4.3 of this rule.~~

~~f. *"Community based pharmacy setting"* means a pharmacy within the state licensed by the West Virginia Board of Pharmacy, where prescription drugs are dispensed and pharmaceutical care is provided by a licensed pharmacist and located outside a hospital inpatient, acute care setting.~~

~~g.~~ 2.8. "Drug therapy management" means the review of drug therapy regimens of patients by a pharmacist for the purpose of evaluating and rendering advice to a physician regarding adjustment of the regimen in accordance with the collaborative pharmacy practice agreement. Decisions involving drug therapy management shall be made in the best interest of the patient. Drug therapy management ~~shall be~~ is limited to:

~~A.~~ 2.8.1. Implementing, modifying, and managing drug therapy according to the terms of the collaborative pharmacy practice agreement;

~~B.~~ 2.8.2. Collecting and reviewing patient histories;

~~C.~~ 2.8.3. ~~Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration~~ Performing patient evaluations that are mutually agreed upon in the collaborative agreement; and

~~D.~~ 2.8.4. Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are also specifically set out in the collaborative pharmacy practice agreement between the pharmacist and physician.

~~**h. "*HIPAA*" means the Health Insurance Portability and Accountability Act of 1996.**~~

~~i. *"Hospital practice protocol"* means a written plan, policy, procedure, or agreement that authorizes drug therapy management between pharmacists and physicians developed and determined by the hospital's P and T committee (or similar committee) and approved by the three boards. Such a protocol may apply to all pharmacists and physicians at a hospital and only to those pharmacists and physicians who are specifically recognized as engaging in collaborative drug therapy management by the hospital. A hospital practice protocol shall comply with the requirements of paragraph 4.6 of this rule.~~

~~**j. "*OSHA*" means the Occupational Safety and Health Administration.**~~

2.9. "Pharmacist Care" means the provision by a pharmacist of patient care activities, with or without the dispensing of drugs or devices, 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 and as provided for in W. Va. Code § 30-5-10.

~~k.~~ 2.10. "*Pharmacist's scope of practice pursuant to the collaborative pharmacy practice agreement*" means those duties and limitations of duties placed upon the pharmacist by the collaborating physician~~, as jointly approved by the Board of Pharmacy and the Board of Medicine or the Board of Osteopathy~~.

~~l. "*P and T committee*" means the pharmacy and therapeutics committee or similar committee established within the hospital setting.~~

~~m. "*Rural health care clinic*" means a non-profit, freestanding primary care clinic in a medically underserved or health professional shortage area.~~

2.11. "Practice notification" means a written notice to the appropriate licensing board that an individual physician or physician group or a medical provider in training where the agreement is signed by the supervising physician or chairperson of the medical department where the medical provider in training is practicing, and an individual pharmacist or pharmacists will practice in collaboration.

2.12. "Website" means the set of related web pages operated by or on behalf of the boards located at the domain names of wvbop.com, wvbom.wv.gov, and wvbdosteo.org or at any successor domain name published by the boards.

§11-8-3. ~~General Rules for~~ Requirements for Collaborative Pharmacy Practice ~~Authority~~.

3.1. Pharmacists and physicians may engage in collaborative pharmacy practice ~~No pharmacist or physician may engage in collaborative pharmacy practice except~~ in accordance with the provisions of this rule.

3.2. Collaborative pharmacy practice may only occur:

3.2.1. Pursuant to a collaborative pharmacy practice agreement developed in accord with this rule; and

3.2.2. Once a complete and valid practice notification is filed with the boards.

3.2~~3~~. ~~Any physician seeking the assistance of a pharmacist for the purpose of collaborative pharmacy~~

~~practice must hold an unrestricted, active license to practice as a physician in West Virginia and the authority granted by the physician must be within the scope of the physician's practice.~~ A physician's eligibility to serve as a collaborating physician may be verified through information available on the websites of the Board of Medicine and Board of Osteopathic Medicine. Physicians who are eligible to collaborate with pharmacists shall ensure that pharmacy collaboration remains within:

3.3.1. The medical specialty and scope of the physician's practice; and

3.3.2. The education, training and experience of the collaborating pharmacist.

3.~~3~~4. ~~Any pharmacist seeking to assist the physician in collaborative pharmacy practice must~~ The Board of Pharmacy shall verify a pharmacist's eligibility to enter into collaborative pharmacy practice agreements upon receipt of an eligibility verification request which is accompanied by satisfactory documentation that the pharmacist:

~~a. Have~~ 3.4.1. Has an unrestricted and current license to practice as a pharmacist in West Virginia;

~~b. Have~~ 3.4.2. Has at least one million dollars of professional liability insurance coverage; and

~~c.~~ 3.4.3. Meets one of the following eligibility criteria: ~~qualifications, at a minimum~~:

~~A.~~3.4.3.a. The pharmacist ~~E~~earned a Certification from the Board of Pharmaceutical Specialties, ~~is a Certified Geriatric Practitioner~~, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, ~~which includes~~ and two years of experience~~d~~ verified by the Board of Pharmacy ~~approved by the appropriate boards~~;

~~B.~~3.4.3.b. The pharmacist ~~S~~successfully completed the course of study and holds an academic degree of Doctor of Pharmacy and has three years of clinical experience ~~approved~~ verified by the Board of Pharmacy and has completed an Accreditation Council for Pharmacy Education (ACPE) approved certificate program in the area of practice covered by the collaborative pharmacy practice agreement; or

~~C.~~3.4.3.c. The pharmacist ~~S~~successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has five years clinical experience ~~approved~~ verified by the Board of Pharmacy ~~appropriate boards~~ and has completed two ACPE approved certificate programs with at least one program in the area of practice covered by the collaborative pharmacy practice agreement.

3.~~4~~5. Eligible pharmacists and physicians may enter into collaborative pharmacy practice agreements in any practice setting. Collaborative pharmacy practice agreements must contain all required elements set forth in section 4 of this rule. ~~Documentation of requirements for collaborative pharmacy practice shall be submitted to and approved as satisfactory by the appropriate licensing boards with jurisdiction over the physician and pharmacist wishing to engage in collaborative pharmacy practice prior to engaging in collaborative pharmacy practice.~~

~~3.5. The approval process to engage in collaborative practice shall be:~~

~~a. The pharmacist shall submit an application for collaborative pharmacy practice to the West Virginia Board of Pharmacy with the applicable fee of $50. Upon approval of that application:~~

~~b. The pharmacist and physician shall submit the collaborative pharmacy practice protocol to the appropriate licensing board with jurisdiction over the subject physician. Upon approval of the protocol by~~

~~the appropriate board, the subject pharmacist and physician may enter into collaborative pharmacy practice agreements with patients for their drug therapy management pursuant to the authorized protocol. The hospital protocol shall be submitted by the P and T committee for approval by all three boards.~~

3.6. Prior to commencing practice pursuant to a collaborative pharmacy practice agreement, the parties shall file a complete practice notification with the Board of Pharmacy.

3.7. A practice notification shall be submitted on a form approved by the boards and shall be accompanied by a $50 fee payable to the Board of Pharmacy. The practice notification form shall be published on the boards' websites.

3.8. A practice notification shall include:

3.8.1. The full name, license number, licensing board, preferred mailing address, telephone number, and email address of the pharmacist(s) and physician(s) who are entering into a collaborative pharmacy practice agreement;

3.8.2. The name and address of each location where the pharmacist will engage in collaborative pharmacy practice pursuant to the agreement;

3.8.3. The proposed effective date of the collaborative pharmacy practice agreement;

3.8.4. Certification by the collaborating pharmacist and collaborating physician that:

3.8.4.a. The pharmacist has been verified as eligible for collaborative pharmacy practice by the Board of Pharmacy;

3.8.4.b. The physician is eligible to serve as a collaborating physician;

3.8.4.c. A collaborative pharmacy practice agreement has been agreed upon and executed by the pharmacist and physician which is consistent with the physician's scope of practice, the pharmacist's education, training and experience, and includes, at a minimum, the protocols required by section 4 of this rule;

3.8.4.d. The collaborating pharmacist will maintain a copy of the collaborative pharmacy practice agreement at his or her place of practice and the parties will provide a copy to any of the boards, upon request;

3.8.4.e. Collaborative pharmacy practice shall only occur after informed consent of the patient, which must be noted in the patient medical record; and

3.8.4.f. The parties acknowledge that the collaborative pharmacy practice agreement does not include the management of controlled substances.

3.9. A complete practice notification is effective upon filing, remains valid until the collaborative pharmacy practice agreement terminates, and is not subject to renewal or renewal fees.

3.10. The boards shall acknowledge receipt of all practice notifications. If a practice notification is incomplete or appears to be invalid, the Board of Pharmacy shall contact the collaborating pharmacist about any issue of validity and any information needed to complete the practice notification. The Board of Pharmacy may request the assistance of the Board of Medicine or the Board of Osteopathic Medicine to evaluate or respond to any issues of practice notification completeness or validity.

3.11. Within five business days of receiving a complete, valid practice notification, the Board of Pharmacy shall confirm receipt to the collaborating pharmacist and provide a copy of the practice notification to the collaborating physician's licensing board. Within five days of receipt of the practice notification from the Board of Pharmacy, the Board of Medicine or Board of Osteopathic Medicine shall notify the collaborating physician.

3.12. The boards shall maintain a current list of all practice notifications for collaborative pharmacy practice agreements.

§11-8-4. Collaborative Pharmacy Practice Agreements ~~Protocols~~.

~~4.1. Collaborative pharmacy practice protocols and any changes or modifications thereto shall be submitted to and approved as satisfactory by the appropriate licensing boards with jurisdiction over the subject physician and pharmacist prior to their engaging in collaborative pharmacy practice.~~

~~4.2. A pharmacist may not practice outside the scope of the protocol approved as satisfactory by the appropriate licensing boards with jurisdiction over the subject physician and pharmacist.~~

~~4.3. Community practice protocol may authorize the following:~~

~~a. Prescription drug orders. The protocol may authorize modification of drug dosages based on symptoms or laboratory or physical findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the patient's physician. The protocol may not authorize the pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.~~

~~b. Laboratory tests. The protocol may authorize the pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management. Only the laboratory tests specified in the agreement may be ordered by the pharmacist. Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center. All laboratory results obtained are to be sent to the physician within forty-eight hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately.~~

~~c. Physical findings. The protocol may authorize the pharmacist to check only these findings: vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the patient's physician for follow-up. Pharmacists shall not conduct any physical examination of the patient other than taking vital signs.~~

~~d. Patient activities. The protocol may authorize the pharmacist to monitor specific patient activities.~~

~~e. Procedures for securing the patient's written consent. The patient's consent must be secured by the physician.~~

~~f. Circumstances that shall cause the authorized pharmacist to initiate communication with the physician including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction. All evaluation notes shall be in the physician's patient's chart within one week of the evaluation and drug management change.~~

~~g. A detailed statement identifying the specific drugs, laboratory tests, and physical findings upon which the authorized pharmacist shall base drug therapy management decisions. Adjustments to drug therapy management must be co-signed by the physician within one week. A pharmacist may not~~

~~begin new medicines without direct consultation and with documentation by the physician nor may the medication be discontinued.~~

~~h. A provision for the collaborative drug therapy management protocol to be reviewed, updated, and re-executed or discontinued at least every two years.~~

~~i. A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician.~~

~~j. A description of the types of reports the authorized pharmacist is to provide to the physician and the schedule by which the pharmacist is to submit these reports. The schedule shall include a time frame within which a pharmacist shall report any adverse reaction to the physician.~~

~~k. A statement of the medication categories and the type of initiation and modification of drug therapy that the physician authorizes the pharmacist to perform. Flu shots and pneumonia injections may be given by the pharmacist to adults only provided that the pharmacist submits evidence of completed certification to give injections and in basic cardiac life support to the appropriate boards and is certified to give injections.~~

~~l. A description of the procedures or plan that the pharmacist shall follow if the pharmacist modifies a drug therapy.~~

~~m. Procedures for record keeping, record sharing, and long-term record storage.~~

~~n. Procedures to follow in emergency situations.~~

~~o. A statement that prohibits the authorized pharmacist from delegating drug therapy management to anyone other than another authorized pharmacist who has signed the applicable protocol.~~

~~p. A statement that prohibits a physician from delegating collaborative drug therapy management to any unlicensed or licensed person other than another physician or an authorized pharmacist.~~

~~q. A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy. The physician shall see the patient every three months and pharmacist visits may not be substituted for such physician visits.~~

~~4.4. A hospital's P and T committee shall determine the scope and extent of collaborative drug therapy management practices that may be conducted by the hospital's pharmacists and it then must be approved by the three boards.~~

~~4.5. Collaborative drug therapy management within a hospital setting is valid only when approved by the hospital's P and T committee and approved by the three boards.~~

~~4.6. The hospital practice protocol shall include:~~

~~a. The names or groups of pharmacists and physicians who are authorized by the P and T committee to participate in collaborative drug therapy management, and approved by the three boards.~~

~~b. A plan for development, training, administration, and quality assurance of the protocol.~~

~~c. A detailed written protocol pursuant to which the hospital pharmacist shall base drug therapy management decisions for patients. The protocol shall authorize one or more of the following:~~

~~1. Medication orders and prescription drug orders. The protocol may authorize modification of drug dosages based on symptoms or laboratory findings defined in the protocol. The protocol shall include information specific to the dosage, frequency, duration, and route of administration of the drug authorized by the physician. The protocol shall not authorize the hospital pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.~~

~~2. Laboratory tests. The protocol may authorize the hospital pharmacist to obtain or to conduct specific laboratory tests as long as the tests relate directly to the drug therapy management.~~

~~3. All orders are verbal orders from the physician and must be co-signed by the physician.~~

~~4. Physical findings. The protocol may authorize the hospital pharmacist to check certain findings, vital signs, oximetry, or peak flows, that enable the pharmacist to assess and adjust the drug therapy, detect adverse drug reactions, or determine if the patient should be referred back to the physician for follow-up.~~

~~5. The physician must request the assistance of the pharmacist in the hospital setting before the pharmacist may begin assistance with the patients' drug therapy management.~~

~~d. Circumstances that shall cause the hospital pharmacist to initiate communication with the patient's physician including but not limited to the need for new medication orders and prescription drug orders and reports of a patient's therapeutic response or adverse reaction. All orders are verbal orders which must be co-signed by the physician.~~

~~e. A statement of the medication categories and the type of initiation and modification of drug therapy that the P and T committee authorizes the hospital pharmacist to perform.~~

~~f. A description of the procedures or plan that the hospital pharmacist shall follow if the hospital pharmacist modifies a drug therapy.~~

~~g. A description of the mechanism for the hospital pharmacist and the patient's physician to communicate and for the hospital pharmacist to document implementation of the collaborative drug therapy. All orders are verbal orders which must be co-signed by the physician.~~

4.1. Collaborative pharmacy practice agreements are voluntarily implemented by practitioners who seek to serve patients with active pharmacist participation in drug therapy management and other related protocols.

4.2. Collaborative pharmacy practice is a collaborative, physician-directed approach which may be utilized after informed consent is received from the patient and recorded in the patient medical record.

4.3. A collaborative pharmacy practice agreement shall establish the pharmacist's scope of practice for purposes of the agreement.

4.4. A pharmacist may not diagnose patients.

4.5. Collaborative pharmacy practice agreements shall be in writing. All pharmacists and physicians who are parties to the agreement shall sign the agreement, and copies of the agreement shall be made available to all individuals collaborating thereunder.

4.6. Collaborating pharmacists shall maintain a copy of the collaborative practice agreement at their place of practice.

4.7. Collaborative practice agreements shall incorporate protocols containing detailed direction concerning the services that collaborating pharmacists may perform for patients and the role of collaborating physicians. The protocols shall, at a minimum, include:

4.7.1. The specific drug or drugs to be managed by the collaborating pharmacist, and the terms and conditions under which drug therapy may be implemented, modified, or discontinued, including:

4.7.1.a. The protocols may authorize implementation or modification of drug dosages based on symptoms or laboratory or patient evaluations defined in the protocol;

4.7.1.b. The protocol shall include information specific to the drugs authorized by the collaborating physician;

4.7.1.c. In instances where drug therapy is discontinued, the pharmacist shall notify the treating physician of the discontinuance within seventy-two hours unless the protocol incorporates a shorter time period for notice;

4.7.1.d. Specific protocols for patients identified by the collaborating physician as having complex medical conditions or comorbidities, one or more of which are under treatment by another medical provider or specialist;

4.7.1.e. The protocol may not authorize the pharmacist to change a controlled substance or to initiate a drug not included in the established protocol.

4.7.2. The conditions and events upon which the pharmacist is required to notify the physician, including but not limited to the need for new prescription orders and reports of the patient's therapeutic response or adverse reaction. All evaluation notes shall be in the patient's medical record within one week of the evaluation and/or drug management change. If there are no drug therapy changes the information shall be provided to the physician within 30 days unless the protocol incorporates a shorter time period for such notice;

4.7.3. The laboratory tests that may be ordered in accordance with drug therapy management, including:

4.7.3.a. Authorization of the collaborating pharmacist to obtain or to conduct specific laboratory tests related to the drug therapy management;

4.7.3.b. The collaborating pharmacist may only obtain the laboratory tests specified in the collaborative pharmacy practice agreement;

4.7.3.c. Laboratories utilized by the pharmacist may be in a pharmacy or pharmacy center; and

4.7.3.d. All laboratory results obtained are to be sent to the physician within forty-eight hours, except that any severely abnormal or critical values shall be sent by the pharmacist to the physician immediately;

4.7.4. The mutually agreed upon patient evaluations the pharmacist may conduct;

4.7.5. The protocol may authorize the pharmacist to monitor specific patient activities;

4.7.6. Procedures for documenting patient informed consent in the patient's medical record;

4.7.7. A provision for the collaborative drug therapy management protocol to be reviewed, updated, and re-executed or discontinued at least every two years;

4.7.8. A description of the method the pharmacist shall use to document the pharmacist's decisions or recommendations for the physician;

4.7.9. Procedures for record keeping, record sharing, and long-term record storage.

4.7.10. Procedures to follow in emergency situations.

4.7.11. A description of the mechanism for the pharmacist and the physician to communicate with each other and for documentation by the pharmacist of the implementation of collaborative drug therapy. Pharmacist visits may not be substituted for physician visits.

4.8. A copy of the protocols set forth in the collaborative pharmacy practice agreement shall be filed in the patient's medical record.

4.9. A collaborating pharmacist may not delegate drug therapy management to anyone other than another collaborating pharmacist that has signed the applicable protocol.

4.10 A collaborating physician may not delegate collaborative drug therapy management to any unlicensed person or licensed person other than another physician, a collaborating physician assistant or a collaborating pharmacist.

§11-8-5. Termination of Collaborative Pharmacy Practice Agreements ~~Protocols~~.

5.1. ~~The protocol(s) may be terminated upon written notice by the subject patient, the pharmacist or the physician, which notice shall be provided to the appropriate boards with jurisdiction and to the other parties, (subject patient) all within fifteen days of termination.~~ A collaborative pharmacy practice agreement automatically terminates if either the collaborating pharmacist(s) or collaborating physician(s) are no longer eligible to collaborate. If multiple practitioners are parties to the agreement, it shall not automatically terminate as long as there is at least one collaborating pharmacist and physician remaining.

5.2. A collaborative pharmacy practice agreement may be terminated at any time by any of the parties to the agreement.

5.3. A collaborating pharmacist shall notify the Board of Pharmacy in writing within ten days of the termination of an active collaborative pharmacy practice agreement.

5.4. The Board of Pharmacy shall notify the collaborating physician's licensing board within five days of receiving notice of termination of a collaborative pharmacy practice agreement.

5.5. A patient may, at any time, revoke consent for collaborative pharmacy practice. Immediately upon withdrawal of patient consent, collaborative pharmacy practice with respect to the non-consenting patient shall cease. Collaboration may continue pursuant to the collaborative pharmacy practice agreement with respect to other patients.

~~**§11-8-6. Fee.**~~

~~6.1. Each application for collaborative pharmacy practice is subject to a $50 fee payable to the West Virginia Board of Pharmacy.~~

~~6.2. Each protocol is subject to a $100 processing fee payable by the physician to the appropriate~~

~~board. Requested modifications in between the two-year period of existence of each protocol are subject to the fee.~~

§11-8-~~7~~6. Ethics.

~~7~~6.1. There shall be no advertising of any collaborative pharmacy practice by either the physician or the pharmacist.

~~7~~6.2. No physician may be employed by any pharmacist or pharmacy for the purpose of collaborative pharmacy practice.

~~7~~6.3. No pharmacist or pharmacy shall make any direct or indirect referral to any physician or medical clinic for the purpose of collaborative pharmacy practice.

~~7~~6.4. Nothing in this rule shall be interpreted to permit a pharmacist to accept delegation of a physician's authority outside the limits included in the appropriate board's statute and rules.

6.5. Pharmacists and physicians who collaborate shall not allow an employment arrangement to:

6.5.1. Interfere with sound clinical judgment;

6.5.2. Diminish or influence the practitioners' ethical obligation to patients; or

6.5.3. Exert undue influence on, or interfere with the robustness of, the collaborative relationship.

§11-8-~~8~~7. Reporting and Discipline.

~~8~~7.1. ~~Either~~ Any or all of the appropriate licensing boards shall have the right to cancel any collaborative pharmacy practice agreement if there is satisfactory evidence that either the physician or pharmacist signatories to the agreement are not acting in accordance with the agreement.

~~8~~7.2. Each appropriate board with jurisdiction of either of the signatories to the agreement shall report to the other appropriate board any acts which it believes are in violation of any ~~approved~~ agreement.

~~8~~7.3. Any physician or pharmacist signatory to a collaborative pharmacy agreement shall be subject to additional monitoring and education or to disciplinary proceedings by the appropriate boards if the subject physician or pharmacist violates the terms of the collaborative pharmacy practice agreement. The licensure denial, complaint and disciplinary process and procedures and appeal rights set forth in each boards' practice act and rules shall apply to their respective licensees in connection with allegations of professional misconduct in connection with pharmacist-physician collaboration.

7.4. In their discretion, the boards may refer and receive information from one another concerning:

7.4.1. Mutual registrants and/or respective licensees;

7.4.2. Information developed during the complaint and investigation process of one board which implicates or otherwise relates to applicants, registrants and/or licensees of another board;

7.4.3. Any complaints received or discovered by one board which relate to mutual applicants, registrants and/or licensees or applicants, registrants and/or licensees of the other board.

7.5. It is dishonorable, unethical or unprofessional conduct for a pharmacist or a physician to engage

in collaborative pharmacy practice without first entering into a written agreement which comports with the requirements of this rule and filing a complete practice notification with the boards through the process described in section 3 of this rule.

~~**§11-8.9. Pilot Project Sites.**~~

~~9.1. Up to five pilot project sites in the community based pharmacy setting may be jointly selected by the Boards of Medicine, Pharmacy, and Osteopathy.~~

~~9.2. In jointly selecting the pilot project sites, the following criteria shall be met:~~

~~a. There must be a designated patient care area for private conversation;~~

~~b. There must be the ability to perform appropriate laboratory testing and to take vital signs;~~

~~c. There must be the capability of keeping comprehensive patient records in a HIPAA compliant manner;~~

~~d. Equipment must be maintained in an OSHA compliant and CLIA waived manner with appropriate records kept; and~~

~~e. A maximum of one not for profit rural health care clinic may be given preference.~~

~~9.3. Outcome Measurements~~

~~a. A report of outcomes from the up to five pilot community pharmacy sites shall be submitted for review by the appropriate legislative committee by January 31, 2010, with copies to the three boards. The measurements may include clinical, humanistic, and economic outcomes indicators.~~