



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia
Secretary Of State

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE**

AGENCY: Medicine TITLE-SERIES: 11-08
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: Collaborative Pharmacy Practice
CITE STATUTORY AUTHORITY: W. Va. Code §30-5-7(c).

The above rule has been authorized by the West Virginia Legislature.

Authorization is cited in (house or senate bill number) Senate Bill 361

Section §64-9-10(c) Passed On 3/11/2023 12:00:00 AM

This rule is filed with the Secretary of State. This rule becomes effective on the following date:

June 1, 2023

This rule shall terminate and have no further force or effect from the following date:

August 01, 2028

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.

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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 §30-5-7(c).

1.3. Filing date. -- May 10, 2023

1.4. Effective date. -- June 1, 2023

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

§11-8-2. Definitions.

For purposes of this rule, the following definitions apply:

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.

2.4. “Collaborative pharmacy practice” is that practice of pharmacist 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.

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.

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.

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 is limited to:

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

2.8.2. Collecting and reviewing patient histories;

2.8.3. Performing patient evaluations that are mutually agreed upon in the collaborative agreement; and

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.

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.

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.

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. Requirements for Collaborative Pharmacy Practice.

3.1. Pharmacists and physicians may engage in collaborative pharmacy practice 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.

3.3. 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.

3.4. 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:

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

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

3.4.3. Meets one of the following eligibility criteria:

3.4.3.a. The pharmacist earned a Certification from the Board of Pharmaceutical Specialties, or has completed an American Society of Health System Pharmacists (ASHP) accredited residency program, and two years of experience verified by the Board of Pharmacy;

3.4.3.b. The pharmacist successfully completed the course of study and holds an academic degree of Doctor of Pharmacy and has three years of clinical experience 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

3.4.3.c. The pharmacist successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has five years clinical experience verified by the Board of Pharmacy 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.

3.5. 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.

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.

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.

5.1. 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. Ethics.

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

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

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.

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.

§11-8-7. Reporting and Discipline.

7.1. 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.

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 agreement.

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;

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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.