11CSR8

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 Osteopathy for legislative approval pertaining to a pharmacist's scope of practice pursuant to collaborative pharmacy practice and collaborative pharmacy practice agreements, and the selection of up to five pilot project sites in the community based pharmacy setting for collaborative pharmacy practice.

1.2. Authority. -- W. Va. Code §30-5-28.

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

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

§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.

b. "*Collaborative pharmacy practice*" is that practice of pharmacy 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. "*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. "*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.

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. "*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 limited to:

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

B. Collecting and reviewing patient histories;

C. Obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration;

D. Ordering screening laboratory tests that are dose related and specific to the patient's medication or are protocol driven and are 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.

k. "*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.

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

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

3.2. 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.

3.3. Any pharmacist seeking to assist the physician in collaborative pharmacy practice must:

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

b. Have at least one million dollars of professional liability insurance coverage;

c. Meet one of the following qualifications, at a minimum:

A. 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 two years of experienced approved by the appropriate boards;

B. Successfully completed the course of study and holds an academic degree of Doctor of Pharmacy and has three years of clinical experience approved by the Board 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. Successfully completed the course of study and holds the academic degree Bachelor of Science in Pharmacy and has five years clinical experience approved by the 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. 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.

§11-8-4. Collaborative Pharmacy Practice 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.

§11-8-5. Termination of 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.

§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. Ethics.

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

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

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

7.4. 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.

§11-8-8. Reporting and Discipline.

8.1. Either 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.

8.2. 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.

8.3. 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.

§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.