

EMERGENCY REGULATIONS

REGULATIONS OF THE JOINT BOARDS OF PHARMACY AND MEDICINE

18 VAC 110-40-10 et seq.

REGULATIONS GOVERNING COLLABORATIVE PRACTICE AGREEMENTS

18 VAC 110-40-10. Definitions.

The following words and terms, when used in this chapter, shall have the following meaning unless the context clearly indicates otherwise:

“*Agreement*” means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of § 54.1-3300.1 of the Code of Virginia.

“*Committee*” means an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members of the Board of Medicine.

EMERGENCY REGULATIONS

“Pharmacist” means, for the purpose of these regulations, a pharmacist who holds an active license to practice pharmacy from the Virginia Board of Pharmacy and who is a signatory to a collaborative practice agreement.

“Practitioner” means, for the purpose of these regulations and notwithstanding the definition in § 54.1-3401 of the Code of Virginia, a doctor of medicine, osteopathy, or podiatry who writes the order and is directly and ultimately responsible for the care of a patient being treated under an agreement and who holds an active license to practice from the Virginia Board of Medicine.

18 VAC 110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner of medicine, osteopathy, or podiatry involved directly in patient care and a pharmacist involved directly in patient care. The practitioner may designate alternate practitioners, and the pharmacist may designate alternate pharmacists, provided the alternates are also signatories to the agreement and are involved directly in patient care at a location where patients regularly receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient and only after written informed consent from the patient has been obtained by the practitioner who authorizes the patient to participate in the agreement. A copy of the informed written consent from the patient shall be provided to the pharmacist.

EMERGENCY REGULATIONS

1. The patient may decline to participate or withdraw from participation at any time.

2. Prior to giving consent to participate, the patient shall be informed by the practitioner of the cooperative procedures that will be used pursuant to an agreement. The procedures to be followed pursuant to an agreement shall be clearly stated on the informed consent form.

3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive which may impact one of the party's decision to participate in the agreement.

18 VAC 110-40-30. Approval of protocols.

- A. If a practitioner and a pharmacist intend to manage or treat a condition or disease state for which there is not a protocol which is clinically accepted as the standard of care, the practitioner and pharmacist shall submit a proposed protocol for approval. The Committee shall, in accordance with § 9-6.14:11 of the Code of Virginia, receive and review the proposed treatment protocol and recommend approval or disapproval to the boards.

- B. For a proposed treatment protocol in which practitioner oversight increases from that which is the accepted standard of care, approval by the Committee is not required.

EMERGENCY REGULATIONS

C. In order to request a protocol review by the Committee, the practitioner and the pharmacist shall submit:

1. An application and required fee of \$750.
2. Supporting documentation that the protocol follows an acceptable standard of care for the particular condition or disease statement for which the practitioner and the pharmacist intend to manage or treat through an agreement.

18 VAC 110-40-40. Content of an agreement and treatment protocol.

A. An agreement shall contain treatment protocols that are clinically accepted as the standard of care within the medical and pharmaceutical professions.

B. The treatment protocol shall describe the disease state or condition, drugs or drug categories, drug therapies, laboratory tests, medical devices, and substitutions authorized by the practitioner.

C. The treatment protocol shall contain a statement by the practitioner that describes the activities the pharmacist is authorized to engage in, including:

EMERGENCY REGULATIONS

1. The procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management;

2. The procedures the pharmacist shall follow for documentation; and

3. The procedures the pharmacist shall follow for reporting activities and results to the practitioner.

D. An agreement shall be valid for a period not to exceed two years. The signatories shall implement a procedure for reviewing and, if necessary, revising the procedures and protocols of a collaborative agreement at least every two years.

18 VAC 110-40-50. Record retention.

A. Signatories to an agreement shall keep a copy of the agreement on file at their primary places of practice.

B. An order for a specific patient from the prescribing practitioner authorizing the implementation of drug therapy management pursuant to the agreement shall be noted in the patient's medical record and kept on file by the pharmacist.

C. A copy of the informed written consent from the patient shall be maintained in the patient's

EMERGENCY REGULATIONS

medical record and kept on file along with the practitioner's order by the pharmacist in a readily retrievable manner.

18 VAC 110-40-60. Rescindment or alteration of the agreement.

A. A signatory may rescind or a patient may withdraw from an agreement at any time.

B. A practitioner may override the collaborative agreement whenever he deems such action necessary or appropriate for a specific patient.

18 VAC 110-40-70. Compliance with statutes and regulations.

Any collaborative agreement or referral under an agreement governed by this chapter shall be in compliance with the requirements of the Practitioner Self-Referral Act (§ 54.1-2410 et seq. of the Code of Virginia) and with Chapters 29, 33 and 34 of Title 54.1 of the Code of Virginia and regulations promulgated pursuant thereto.