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REGULATIONS JOINTLY ADOPTED BY THE BOARDS OF PHARMACY AND MEDICINE

18 VAC 110-40-10 et seq.

REGULATIONS GOVERNING COLLABORATIVE PRACTICE AGREEMENTS

18VAC110-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings, 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.

"Pharmacist" means 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, 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.

18VAC110-40-20. 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~~ Documented informed consent from the

patient ~~has been~~ shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement. ~~A copy of the informed written consent from the patient shall be provided to the pharmacist.~~

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 or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record. ~~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 that may impact one of the party's decisions to participate in the agreement.

18VAC110-40-30. Approval of protocols outside the standard of care.

A. If a practitioner and a pharmacist intend to manage or treat a condition or disease state for which there is not a protocol that is clinically accepted as the standard of care, the practitioner and pharmacist shall apply for approval ~~submit a proposed protocol for approval~~. The committee shall, in accordance with §~~9-6.14:11~~ 2.2-4019 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.~~ Application and approval is not needed for treatment of conditions for which there is an accepted standard of care, but for which the practitioner wants to increase the monitoring and oversight of the condition over what the protocol recommends.

C. In order to ~~request a protocol review by the committee~~ apply for approval of a protocol outside the standard of care, the practitioner and the pharmacist shall submit:

1. An application and required fee of $750;

2. A copy of the proposed protocol; and

~~2~~ 3. Supporting documentation that the protocol ~~follows an acceptable standard of care~~ is safe and effective for the particular condition or disease state for which the practitioner and the pharmacist intend to manage or treat through an agreement.

18VAC110-40-40. 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:

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 periodically reviewing and, if necessary, revising the procedures and protocols of a collaborative agreement~~ at least every two years~~.

E. If either the practitioner or the pharmacist who is a party to the agreement has a change of location or change of ownership, that person shall notify the other party and all patients who are participants in the collaborative agreement.

18VAC110-40-50. 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 medical record and kept on file along with the practitioner's order by the pharmacist in a readily retrievable manner.~~ The patient's documented informed consent shall be retained by the practitioner in the patient record.