

PROFESSIONS AND OCCUPATIONS: PHARMACY — DRUG CONTROL ACT — MEDICINE AND OTHER HEALING ARTS.

Pharmacist's authority to substitute drug therapy is limited to physician's prescriptive order in treatment protocol contained in collaborative agreement; any deviation or inconsistency with prescribed treatment constitutes grounds for disciplinary action. Proposed emergency regulations promulgated by Boards of Medicine and Pharmacy mirror statutory limitations regarding pharmacist's authority to dispense drugs pursuant to collaborative agreement and treatment protocol prescribed by physician. Boards' interpretation of regulations is entitled to great weight.

The Honorable Phillip Hamilton
Member, House of Delegates
December 27, 1999

You ask whether Chapter 33 of Title 54.1, §§ 54.1-3300 through 54.1-3319 of the *Code of Virginia*, prohibits a pharmacist's therapeutic substitution of chemically dissimilar drugs without the explicit consent of the prescribing physician.

You advise that your request is based on the possibility of a pharmacist entering into a collaborative agreement that would permit a therapeutic substitution of a chemically dissimilar drug without the explicit knowledge of the prescribing physician. You also advise that during the legislative debate at the 1999 Session of the General Assembly, you offered an amendment to clarify this matter. You relate that the amendment was defeated, because the General Assembly thought the issue would be better addressed in the regulatory process.

The 1999 Session of the General Assembly amended and reenacted § 54.1-3300 and added new § 54.1-3300.1.¹ The 1999 amendments to § 54.1-3300 added the definition of "collaborative agreement,"² which means:

a voluntary, written arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a location where patients receive services and a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

Section 54.1-3300.1 provides:

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests or medical devices, under defined conditions and/or limitations, for the purpose of improving patient outcomes. No patient shall be

required to participate in a collaborative procedure without such patient's consent.

Collaborative agreements may include the modification, continuation or discontinuation of drug therapy pursuant to written, patient-specific protocols; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

Section 54.1-3410(A), a portion of The Drug Control Act, §§ 54.1-3400 through 54.1-3472, provides that a pharmacist may sell and dispense drugs pursuant to a prescription as follows:

1. A drug listed in Schedule II shall be dispensed only upon receipt of a written prescription that is properly executed, dated and signed by the person prescribing on the day when issued and bearing the full name and address of the patient for whom, or of the owner of the animal for which, the drug is dispensed, and the full name, address, and registry number under the federal laws of the person prescribing, if he is required by those laws to be so registered. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed;
2. In emergency situations, Schedule II drugs may be dispensed pursuant to an oral prescription in accordance with the ... regulations [of the Board of Pharmacy.]

Section 54.1-3410(B)(1) further provides that Schedule III through VI drugs shall be dispensed as follows:

If the prescription is written, it shall be properly executed, dated and signed by the person prescribing on the day when issued and bear the full name and address of the patient for whom, or of

the owner of the animal for which, the drug is dispensed, and the full name and address of the person prescribing. If the prescription is for an animal, it shall state the species of animal for which the drug is prescribed.

Section 54.1-3457(16) prohibits "[d]ispensing or causing to be dispensed, except as provided in § 32.1-87 relating to the Virginia Voluntary Formulary, a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing."

Both the 1999 enactments to §§ 54.1-3300 and 54.1-3300.1 and the relevant provisions of §§ 54.1-3410 and 54.1-3457 of The Drug Control Act iterate the limitations placed on a pharmacist's authority to dispense drugs pursuant to a collaborative agreement and treatment protocol. It is my opinion that the authority of a pharmacist to dispense drugs is limited to the physician's prescriptive order contained in the treatment protocol, and that to do otherwise would be considered illegal and unprofessional conduct.³

You also inquire whether the prohibition would remain in effect should the proposed emergency regulations developed by the joint Boards of Medicine and Pharmacy ("Boards") be adopted.⁴

The Boards are authorized "[t]o promulgate regulations ... which are reasonable and necessary to administer effectively the regulatory system."⁵ With respect to collaborative agreements, § 54.1-3300.1 expressly authorizes the Boards to "jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists." Pursuant to the 1999 enactment, the Boards "shall ... promulgate regulations to implement the provisions of [§ 54.1-3300.1] within 280 days of the date of enactment. No collaborative agreement shall become effective prior to ninety days after the effective date of the emergency regulations."⁶

"Where a statute is unambiguous, the plain meaning is to be accepted without resort to the rules of statutory interpretation."⁷ "The manifest intention of the legislature, clearly disclosed by its language, must be applied."⁸ "[T]ake the words as written' ... and give them their plain meaning."⁹

The proposed emergency regulations provide that "[a]n agreement^[10] shall contain treatment protocols that are clinically accepted as the standard of care within the medical and pharmaceutical professions."¹¹ The treatment protocol (1) "shall describe the disease state or condition, drugs or drug categories, drug therapies, laboratory tests, medical devices, and substitutions authorized by the practitioner,"¹² and (2) "shall contain a statement by the practitioner that describes the activities [in which] the pharmacist is authorized to engage."¹³ The regulations provide that a practitioner may include in the protocol a statement of

1. [t]he procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management;
2. [t] he procedures the pharmacist shall follow for documentation; and
3. [t]he procedures the pharmacist shall follow for reporting activities and results to the practitioner.^[14]

The regulations also provide that "[a]n 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."¹⁵

The collaborative practice contemplated by the proposed emergency regulations involves a voluntary written agreement whereby a physician refers a patient to a pharmacist to manage and/or treat a specific medical condition or disease in accordance with a clinically accepted treatment protocol. Such a practice is similar to the collaborative practices of a physician's assistant and a licensed nurse practitioner pursuant to §§ 54.1-2952 and 54.1-2957. In both of these advanced practices, a physician may delegate certain acts constituting the practice of medicine consistent with regulations of the Boards of Medicine and Nursing. The collaborative agreement between physicians and pharmacists involves a similar delegation whereby the physician, pursuant to a protocol, describes "[t]he procedures, decision criteria, or plan the pharmacist shall follow when providing drug therapy management."¹⁶

In accordance with the proposed emergency regulations, a pharmacist may alter or change a specific drug therapy only as prescribed by the physician. Such alteration or change may include an increase or decrease in a specific dosage, or it may involve changing drug therapy to another drug product. In both instances, the physician specifically has authorized the pharmacist to make the change in accordance with delineated criteria.¹⁷ The protocol, to the extent it provides for a specific drug therapy, constitutes the prescriptive order of the physician. Therefore, when a pharmacist alters or changes a drug therapy in accordance with the protocol, the pharmacist is merely dispensing drug therapy to a patient pursuant to the direct prescriptive order of a physician.

The proposed regulations clearly and explicitly mirror the statutory limitations regarding a pharmacist's authority to dispense drugs pursuant to a collaborative agreement and treatment protocol.¹⁸ Based on the assumption that the current statutory provisions specifically limit a pharmacist's authority to change or alter a physician's order, any increase or decrease in the dosage or change in a drug product (i.e., a chemically dissimilar drug) must, therefore, be prescribed by the physician.¹⁹ To the extent the protocol provides for a specific drug therapy, it constitutes the prescriptive order of the physician. Whenever a pharmacist alters or changes the drug therapy in accordance with the protocol, the pharmacist does so at the direction of the physician's order. In such a situation, the pharmacist is not prescribing but is merely following the physician's instructions to dispense a drug.

Moreover, since the Boards are the agencies charged with the administration of §§ 54.1-3300 and 54.1-3300.1, their interpretation is entitled to great weight.²⁰ The proposed emergency regulations of the Board are consistent with the 1999 enactments concerning collaborative agreements and the relevant provisions of The Drug Control Act, and unless that interpretation is clearly wrong, it carries great weight and is entitled to deference. I must, therefore, decline to respond formally to this final question.

¹1999 Va. Acts chs. 895, 1011, at 1716; 2687, respectively. Both acts expire July 1, 2004. See *id.* cl. 2, at 1717, 2688.

²See *id.* ch. 895, at 1716-17; ch. 1011, at 2687.

³See § 54.1-2902 (making practice of medicine unlawful without valid license issued by Board of Medicine); § 54.1-3316 (listing conduct that results in revocation, suspension or denial of license by Board of Pharmacy).

⁴I am advised that an ad hoc committee of the Boards, with representatives from the Virginia Medical Society and the Virginia Pharmaceutical Association, is considering regulations governing collaborative practice agreements. See proposed Regulations of the Joint Boards of Pharmacy and Medicine Governing Collaborative Practice Agreements (June 20, 1999) [hereinafter draft regs] (on file with Department of Professional and Occupational Regulation).

⁵Section 54.1-2400(6).

⁶1999 Va. Acts, *supra* note 1, chs. 895, 1011, at 1717, 2688, respectively (quoting cl. 3).

⁷Last v. Virginia State Bd. of Medicine, 14 Va. App. 906, 910, 421 S.E.2d 201, 205 (1992).

⁸Barr v. Town & Country Properties, 240 Va. 292, 295, 396 S.E.2d 672, 674 (1990) (quoting Anderson v. Commonwealth, 182 Va. 560, 566, 29 S.E.2d 838, 841 (1944)).

⁹Adkins v. Com., 27 Va. App. 166, 169, 497 S.E.2d 896, 897 (1998) (quoting Birdsong Peanut Co. v. Cowling, 8 Va. App. 274, 277, 381 S.E.2d 24, 26 (1989)).

¹⁰The draft regs define "agreement" as "a collaborative practice agreement." See draft regs, *supra* note 4, at 1 (to be codified at 18 VAC 110-40-10).

¹¹*Id.* at 2 (to be codified at 18 VAC 110-40-40(A)).

¹²*Id.* (to be codified at 18 VAC 110-40-40(B)).

¹³*Id.* (to be codified at 18 VAC 110-40-40(C)).

¹⁴*Id.* at 2-3 (to be codified at 18 VAC 110-40-40(C) (1-3)).

¹⁵*Id.* at 3 (to be codified at 18 VAC 110-40-50(B)).

¹⁶*Id.* at 2 (quoting proposed 18 VAC 110-40-40(C)(1)); see also § 54.1-3408(A) (authorizing licensed pharmacists, registered nurses or licensed practical nurses to administer vaccines to adults for immunization, pursuant to protocol approved by Board of Nursing, when prescribing practitioner is not physically present).

¹⁷See *id.* at 2-3 (citing proposed 18 VAC 110-40-40(C)(1-3), 110-40-50(B)).

¹⁸See §§ 54.1-3300, 54.1-3300.1, 54.1-3410(A), (B), 54.1-3457.

¹⁹See draft regs, *supra* note 4, at 2-3 (citing proposed 18 VAC 110-40-40(C)(1-3), 110-40-50(B)).

²⁰It is an elementary rule of statutory interpretation that the "construction given to a statute by public officials charged with its enforcement is entitled to great weight ... and in doubtful cases will be regarded as decisive." *Bed Company v. Corporation Commission*, 205 Va. 272, 275, 136 S.E.2d 900, 902 (1964) (citing *Commonwealth v. Appalach. El. Power Co.*, 193 Va. 37, 45, 68 S.E.2d 122, 127 (1951)).