

HEALTH: MEDICAL CARE SERVICES - VIRGINIA VOLUNTARY FORMULARY.

PROFESSIONS AND OCCUPATIONS: DRUG CONTROL ACT — PHARMACY - BOARD OF PHARMACY — DEPARTMENT OF HEALTH PROFESSIONS — GENERAL PROVISIONS.

Authority for Board of Pharmacy to promulgate regulations governing form of documented consent required for pharmacists to substitute or interchange narrow therapeutic index drug. No requirement to promulgate separate regulations specifying manner or type of documented consent required of patient's prescriber should Board determine that statutory requirement for printing of Voluntary Formulary substitution check boxes on prescription forms is sufficient form of consent.

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You ask whether § 32.1-87(C) provides sufficient authority for the Board of Pharmacy ("Board") to promulgate regulations governing the form of consent required for pharmacists to substitute or interchange a "narrow therapeutic index drug." If so, you also ask whether the Board is required to promulgate such regulations should it determine the regulations to be unnecessary because of the Formulary substitution "check boxes" directed by §§ 32.1-87(A)¹ and 54.1-3408(C)² to be printed on prescription forms.

Your inquiry arises from the addition by the 1997 Session of the General Assembly of subsection C to § 32.1-87,³ which becomes effective July 1, 1998. The first paragraph of § 32.1-87(C) states:

Narrow therapeutic index drugs include: carbamazepine, digoxin, levothyroxine, phenytoin, theophylline sustained release, and warfarin. A pharmacist shall not substitute or interchange a narrow therapeutic index drug, as defined in § 32.1-79 and identified in this subsection, without the documented consent of the patient's prescriber to the substitution or interchange to the extent required by regulations promulgated by the Board of Pharmacy consistent with its regulatory powers and with the advice of the Voluntary Formulary Board.

At its 1997 Session, the General Assembly also added to § 32.1-79 a definition of the term "narrow therapeutic index drugs," which means "those pharmaceuticals having a more defined range between risk and benefit. Such drugs are known to have less than a two-fold difference in the minimum toxic concentration and minimum effective concentration in the blood."⁴ Narrow therapeutic index drugs are included in the Voluntary Formulary.⁵ The Assembly, however, did not amend § 54.1-3408(C) to include the last two paragraphs added in § 32.1-87(A), relating to the responsibility of the prescribing physician and pharmacist in the use of a generic drug substitute, and the form of the printed prescription label to be used.⁶

You first ask whether § 32.1-87(C) provides sufficient authority for the Board to promulgate regulations governing the form of consent required for pharmacists to substitute or interchange a "narrow therapeutic index drug."

The primary object in interpreting a statute is to ascertain and give effect to the legislative intent underlying the statute. "The ascertainment of legislative intention involves appraisal of the subject matter, purposes, objects and effects of the statute, in addition to its express terms."⁷ It is, however, unnecessary to resort to any rules of statutory construction where the language of a statute is clear and unambiguous.⁸ In such instances, the statute must be given its "plain, obvious, and rational meaning."⁹ The language in § 32.1-87(C) is plain and unambiguous: "A pharmacist shall^[10] not substitute or interchange a narrow therapeutic index drug" without having documentation from the patient's prescriber consenting to such substitution or interchange, consistent with regulations promulgated by the Board.

The General Assembly requires the Board to "regulate the practice of pharmacy."¹¹ In so regulating the practice of pharmacy, the Board must consider, among other criteria, "[c]ompliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use."¹² The clear language of § 32.1-87(C) permits the Board to promulgate regulations "consistent with its regulatory powers." It, therefore, is my opinion that § 32.1-87(C) provides authority, effective July 1, 1998, for the Board to promulgate regulations, consistent with its regulatory powers, governing the form of the "documented consent" required before pharmacists may substitute or interchange "a narrow therapeutic index drug."

You next ask whether § 32.1-87(C) requires the Board to promulgate regulations governing the form of consent for substitution of a narrow therapeutic index drug if it determines that such regulations are unnecessary because of the Formulary substitution check boxes directed by §§ 32.1-87(A) and 54.1-3408(C) to be printed on prescription forms.

The Board is the agency charged with the administration of § 32.1-87(C).¹³ Therefore, its interpretation of § 32.1-87(C) is entitled to great weight.¹⁴ While the interpretation of this section by the Board must not be inconsistent with the statutes, because of the Formulary substitution check boxes directed by §§ 32.1-87(A) and 54.1-3408(C) to be printed on prescription forms, the determination by the Board that additional regulations are unnecessary carries great weight and, unless clearly wrong, is entitled to deference.¹⁵

The primary object of statutory construction and interpretation is to ascertain and give effect to the intent of the legislature.¹⁶ To determine legislative intent, statutes dealing with the same subject matter should, to the extent possible, be read together.¹⁷ One of the general powers of the Board, as a health regulatory board,¹⁸ shall be "[t]o promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system."¹⁹ Statutes are to be read in accordance with their plain meaning and intent.²⁰ Consequently, the Board is authorized to promulgate regulations; however, it need only promulgate regulations that are "reasonable and necessary to administer effectively the regulatory system" of the practice of pharmacy.²¹ The Board, therefore, is the agency that must determine regulations that are "reasonable and necessary." When the General Assembly intends a statute to impose mandatory requirements on an agency to promulgate specific regulations, it knows how to express its intention.²²

The clear and unambiguous words of a statute must be accorded their plain meaning.²³ In addition, when a statute creates a specific grant of authority, the authority exists only to the extent specifically granted in the statute. The mention of one thing in such a statute implies the exclusion

of another.²⁴ The language of §§ 32.1-87(C), 54.1-2400(6) and 54.1-3307(2) clearly does not require the Board to promulgate any separate regulations that specify the manner or type of "documented consent" that is required of a patient's prescriber. Consequently, absent the use of any language by the General Assembly in § 32.1-87(C) requiring the Board to promulgate such separate regulations, I am of the opinion that, as of July 1, 1998, § 32.1-87(C) does not require the Board to promulgate any such additional regulations should it determine that such regulations would be unnecessary because of the Formulary substitution "check boxes" directed by §§ 32.1-87(A) and 54.1-3408(C) to be printed on prescription forms.²⁵

¹Section 32.1-87(A) provides: "Use of the Voluntary Formulary by professional and institutional providers of health care shall be voluntary. The prescription form shall include two boxes, one labelled 'Voluntary Formulary Permitted' and the other labelled 'Dispense As Written.' A prescriber may indicate his permission for the dispensing of a drug product included in the Formulary upon signing a prescription form and marking the box labelled 'Voluntary Formulary Permitted.' A Voluntary Formulary product shall be dispensed if the prescriber fails to indicate his preference. Whenever a pharmacist dispenses a Voluntary Formulary product when a prescription is written for a brand name product, the pharmacist shall label the drug with the generic name followed by the words 'generic for' followed by the brand name of the drug for which the prescription is written. If no Voluntary Formulary product is immediately available, or if the patient objects to the dispensing of a generic drug, the pharmacist may dispense a brand name drug.

"On and after July 1, 1993, printed prescription forms shall provide:

" Dispense As Written

" Voluntary Formulary Permitted

"

" Signature of prescriber

"If neither box is marked, a Voluntary Formulary product must be dispensed.'

"If a prescriber orders a drug listed in the Formulary by its generic name, the pharmacist shall dispense a drug product from among those listed in the Formulary.

"In the case of an oral prescription, the prescriber's oral dispensing instructions shall be followed. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so apprise the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label the brand name or, in the case of a generic drug product, the name of the manufacturer or distributor."

²Section 54.1-3408(C) contains language identical to that in § 32.1-87(A) (*see supra* note 1), with the exception of the omissions of the first sentence and last two paragraphs in § 32.1-87(A). The first sentence in § 54.1-3408(C) begins, "Pursuant to § 32.1-87," and continues with the same language contained in the second sentence of § 32.1-87(A).

³1997 Va. Acts ch. 755, at 1805, 1806.

⁴ *Id.*

⁵ See § 32.1-79.

⁶ Compare § 32.1-87(A) (*see supra* note 1) with § 54.1-3408(C) (*see supra* note 2).

⁷ *Vollin v. Arlington Co. Electoral Bd.*, 216 Va. 674, 679, 222 S.E.2d 793, 797 (1976).

⁸ See *Ambrogi v. Koontz*, 224 Va. 381, 386, 297 S.E.2d 660, 662 (1982).

⁹ *Yeatts v. Murray*, 249 Va. 285, 288, 455 S.E.2d 18, 20 (1995).

¹⁰ The use of the word "shall" in a statute ordinarily implies that its provisions are mandatory. See *Andrews v. Shepherd*, 201 Va. 412, 414, 111 S.E.2d 279, 281-82 (1959); *see also* *Schmidt v. City of Richmond*, 206 Va. 211, 218, 142 S.E.2d 573, 578 (1965); *Op. Va. Att'y Gen.*: 1996 at 178, 178; 1991 at 238, 240; 1989 at 250, 251-52; 1985-1986 at 133, 134.

¹¹ Section 54.1-3307.

¹² Section 54.1-3307(2).

¹³ See § 54.1-3307.

¹⁴ See *Forst v. Rockingham*, 222 Va. 270, 276, 279 S.E.2d 400, 403 (1981); *Dept. Taxation v. Prog. Com. Club*, 215 Va. 732, 739, 213 S.E.2d 759, 763 (1975) (construction of statute by state agency charged with its administration is entitled to great weight).

¹⁵ See, *e.g.*, 1996 *Op. Va. Att'y Gen.* 124, 126-27.

¹⁶ See *Turner v. Commonwealth*, 226 Va. 456, 459, 309 S.E.2d 337, 338 (1983).

¹⁷ See *Vollin v. Arlington Co. Electoral Bd.*, 216 Va. at 674, 222 S.E.2d at 793; *Prillaman v. Commonwealth*, 199 Va. 401, 405-06, 100 S.E.2d 4, 7 (1957); *Op. Va. Att'y Gen.*: 1994 at 114, 116; 1993 at 27, 29; 1991 at 161, 165.

¹⁸ See § 54.1-2500 (defining "health regulatory board"); § 54.1-2503 (including Board within Department of Health Professions).

¹⁹ Section 54.1-2400(6).

²⁰ See *Ambrogi v. Koontz*, 224 Va. at 386, 297 S.E.2d at 662.

²¹ Section 54.1-2400(6).

²² See, *e.g.*, § 54.1-3223(A) (requiring that Board of Optometry, another health regulatory board, promulgate regulations governing treatment of certain diseases and abnormal conditions of human eye).

²³ See *Diggs v. Commonwealth*, 6 Va. App. 300, 302, 369 S.E.2d 199, 200 (1988).

²⁴ See *Turner v. Wexler*, 244 Va. 124, 127, 418 S.E.2d 886, 887 (1992) ("*Expressio unius est exclusio alterius*").

²⁵ Such a formal determination by the Board is, in essence, an implied intent that the Formulary substitution "check boxes" directed by §§ 32.1-87(A) and 54.1-3408(C) to be printed on prescription forms constitute a sufficient form of "documented consent" for a prescriber's physician to substitute or interchange a narrow therapeutic index drug, in conformance with § 32.1-87(C).