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The State of South Carolina



Office of the Attorney General

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May 28, 1985

Honorable Nick A. Theodore Member, South Carolina Senate Medical Affairs Committee Post Office Box 142 Columbia, South Carolina 29202

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Dear Senator Theodore:

You have requested an opinion from this Office as to whether or not two proposed regulations, recently promulgated by the South Carolina Board of Pharmacy, "had been promulgated within statutory authority" given to the Board of Pharmacy. Specifically, you have asked two questions:

- (a) "Does Section 40-43-130 or any other provision of the Pharmacy Practice Act give the Board of Pharmacy the authority to promulgate" proposed Regulation 99-40?
- (b) "Does Section 40-43-130 or any other provision of the Pharmacy Practice Act give the Board of Pharmacy the authority to promulgate" proposed Regulation 99-41?

For the reasons set out hereinafter, it is the opinion of this Office that proposed Regulation 99-40 has been promulgated within the statutory authority of the South Carolina Board of Pharmacy (hereinafter "Board"); however, it is the opinion of this Office that proposed Regulation 99-41 is most probably an invalid exercise of the Board's rule-making authority. If the validity of proposed Regulation 99-41 were presented to a court, it is the opinion of this Office that the court would probably rule that proposed Regulation 99-41 is void and unenforceable.

PROPOSED REGULATION 99-40

South Carolina Code §40-43-130 (1976), which sets out certain regulatory powers of the South Carolina Board of Pharmacy, provides:

Honorable Nick A. Theodore Page 2 May 28, 1985

> The Board shall also regulate the practice of pharmacy, the operation of drugstores and pharmacies and the compounding, dispensing and sale of drugs, medicines, poisons and physicians' prescriptions and, in so doing, shall make, publish, supervise and enforce rules and regulations for the practice of pharmacy, the operation of drugstores and pharmacies, the inspection of weights and measures used in the prescription department of drugstores and pharmacies and the compounding, dispensing and sale of drugs, medicines, poisons and physicians' prescriptions. It shall also prescribe and maintain minimum standards of technical equipment and sanitation for prescription departments of drugstores and pharmacies. But nothing herein shall be construed to authorize the Board to make regulations concerning the prices of goods or medicines sold by drugstores or pharmacies, the hours that such businesses may be operated or the hours of work of employees of such businesses. (emphasis added)

Clearly, Section 40-43-130 empowers the Board to regulate the "dispensing" of drugs and to promulgate "rules and regulations" for the dispensing of drugs. $\underline{1}/$

South Carolina Code \$\$40-43-120 and 40-43-130 (1976) carve out exceptions for physicians and hospitals as to the dispensing of drugs:

Nothing in this chapter, however, shall be construed as intending to hinder or prohibit any physician or dentist lawfully engaged in the practice of his profession anywhere within this State from putting up his own prescriptions or dispensing his own medicines. S.C. Code §40-43-120 (1976)

Provided, further, that nothing in \$\$40-43-360 to 40-43-460 shall be construed as preventing any hospital licensed by the State Department of Health and Environmental Control, or owned or operated by an agency of the State or the United States of America, from dispensing drugs to in-patients in the regular course of operation of such hospital. S.C. Code \$40-43-430 (1976)

Honorable Nick A. Theodore Page 3 May 28, 1985

An administrative regulation "is valid as long as it is reasonably related to the purpose of its enabling legislation."

Hunter & Walden Company, Inc. v. South Carolina State Licensing Board for Contractors, et al., 272 S.C. 211, 251 S.E. 2d 186 (1978); Mourning v. Family Publications Service, Inc., 411 U.S. 356, 93 S.Ct. 1652, 36 L.Ed. 2d 318 (1973); 2 Am.Jur.2d, Administrative Law, §296; 73 C.J.S. Public Administrative Bodies and Procedure, §94.

Proposed Regulation 99-40 provides:

99-40. Emergency Dispensing.

Legend drugs may be dispensed in emergency rooms and medical clinics by or under the direct supervision of the physician in charge, in order to meet the immediate needs of the patient. The amount dispensed shall not exceed an amount equal to a twenty-four hour supply. Records of drugs dispensed shall be maintained.

Proposed Regulation 99-40 deals with the dispensing of legend drugs and the attendant recordkeeping requirements. This proposed regulation is a reasonable implementation of §40-43-130 and is promulgated pursuant to valid statutory authority. This conclusion is compelled by an earlier opinion of this Office regarding regulations relating to the dispensation of drugs under specifically defined circumstances. See, Opinion No. 77-84 in which this Office concluded that Regulation 31 which relates to the dispensing of drugs by medical clinics and/or dispensaries was validly promulgated pursuant to appropriate statutory authority. The language of Regulation 31 is strikingly similar to the language in proposed Regulation 99-40.

It is the opinion of this Office that proposed Regulation 99-40 is a valid administrative regulation reasonably related to the purpose of its enabling legislation. 2/

PROPOSED REGULATION 99-41

Proposed Regulation 99-41 (a copy of which is attached hereto) sets out a program of continuing education for pharmacists. The proposed regulation provides, among other requirements, that licensed pharmacists "shall complete, six hours - first year, twelve hours - second year, fifteen hours -

 $[\]frac{2}{}$ Of course, proposed Regulation 99-40 does not purport to alter or redefine the practice of medicine as defined in S.C. Code §40-47-40 (1976, as amended).

Honorable Nick A. Theodore Page 4 May 28, 1985

third year and thereafter, of accredited continuing pharmacy education each pharmacy year, effective July 1, 1987." A pharmacist "who is in violation" of the terms of proposed Regulation 99-41 "shall be automatically suspended from the practice of pharmacy."

South Carolina Code §§40-43-50, 40-43-230, and 40-43-260 (1976, as amended) set out the statutory authority for the licensing of pharmacists, for license renewal, and for license revocation. No where in these statutes nor in the remaining statutes of the Pharmacy Practice Act (S.C. Code §§40-43-10, et seq.) is continuing education mentioned or addressed as either a qualification or a condition of licensing.

As addressed hereinabove, the Board of Pharmacy is to regulate the practice of pharmacy, S.C. Code §40-43-130; however, the Board cannot "materially alter or add to the minimum requirements" regarding the renewal of a pharmacist's license. Brooks v. South Carolina State Board of Funeral Service, 271 S.C. 457, 247 S.E. 2d 820, 822 (1978).

The Brooks decision involved an attempt by the South Carolina State Board of Funeral Service to promulgate a rule regarding the experience qualifications of applicants to take the funeral director licensing examination. The Funeral Board is charged with the responsibility of licensing those persons who wish to engage in embalming or in the profession of funeral directing in South Carolina. S.C. Code §40-19-140 (1976, as amended). The Funeral Board is authorized by S.C. Code §40-19-90 (1976, as amended) to promulgate rules and regulations concerning the practice of embalming and concerning the practice of funeral directing. Section 40-19-90, as written at the time of the Brooks decision, provided in part as follows:

In furtherance of its purpose of regulating the practice of embalming and funeral directing in this State, the Board shall have the power and it shall be its duty to prescribe rules and regulations governing . . . the qualifications, fitness and practices of those engaged in and who may engage in embalming and funeral directing in this State. . .and governing the proper administration of the provisions of this chapter. The Board shall specifically have the power to fix and prescribe rules and regulations as to the procedure to be followed in the making of applications for licenses, in the issuance and renewals of licenses and in the conduct of examinations. (emphasis added)

Honorable Nick A. Theodore Page 5 May 28, 1985

The South Carolina Supreme Court in Brooks, struck down as void and unenforceable a rule which attempted to add to the minimum requirements specified by statute of a funeral director.

Section 40-43-130, which gives the Pharmacy Board the power to promulgate rules and regulations to "regulate the practice of pharmacy," is strikingly similar to Section 40-19-90 which gives the Funeral Board the authority to regulate the "qualifications ... of those... who may engage in embalming and funeral directing. The analogy between the Brooks case and the facts regarding the adoption of proposed Regulation 99-41 is compelling. Proposed Regulation 99-41 sets out a scheme of continuing education which goes beyond the minimum qualifications for licensing and license renewal set out in the Pharmacy Practice Act. Therefore, proposed Regulation 99-41 may well run afoul of the dictates of the <u>Brooks</u> decision which would render proposed Regulation 99-41 void and unenforceable.

While this conclusion is certainly not free from doubt, it is the opinion of this Office that proposed Regulation 99-41 is most probably an invalid exercise of the Pharmacy Board's rule-making authority and, if this question were presented to a court, it is the opinion of this Office that the court probably would rule that proposed Regulation 99-41 is void and unenforceable.

ly yours,

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Senate of South Carolina, Medical Affairs Committee

REVIEWED AND APPROVED BY:

Executive Assistant for Opinions