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The State of South Carolina
OFFICE OF THE ATTORNEY GENERAL

HENRY MCMASTER
ATTORNEY GENERAL

January 29, 2004

The Honorable James H. Harrison
Member, House of Representatives
512 Blatt Building
Columbia, South Carolina 29211

Dear Representative Harrison:

You have requested an opinion regarding an issue recently brought to your attention by the South Carolina Medical Association. The issue involves whether pharmacists in South Carolina are authorized to perform cholesterol testing.

You have included in your request a letter written by a past President of the South Carolina Medical Association which expresses the concerns of the S.C.M.A. as to the current practice of pharmacists who are performing cholesterol testing. The physician is of the opinion that this practice violates the principles of current federal regulations concerning medical laboratory testing. Such regulations are promulgated pursuant to the Clinical Laboratory Improvement Act of 1988. See, 42 U.S.C.A. § 263a; 42 C.F.R. § 493 et seq. In addition, the physician is concerned that the performance of cholesterol tests by pharmacists might lead to possible violations of professional behavior rules, such as inappropriate medical therapeutics recommendations by the pharmacist. Finally, the concern is expressed by the physician that the administration of such tests may constitute the unauthorized practice of medicine by pharmacists who perform these tests. You have requested that we analyze the current federal and state laws applicable to this issue and advise as to the legality of pharmacists performing cholesterol testing in South Carolina.

Law / Analysis

At the outset, it must be emphasized that the question you have presented is novel not only in South Carolina but throughout the United States. We have been unable to find any authority – either case law or opinions of Attorneys General – directly on point. Moreover, the issue is fact specific, and thus only a court may resolve this question with finality; any opinion of the Attorney General is advisory only. With that caveat in mind, we will attempt to address the question which you have presented.

The South Carolina Pharmacy Act is found at S.C. Code Ann. Sections 40-43-10 et seq. The Act establishes statutory criteria for the regulation of the practice of pharmacy as well as the scope

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of activities performed by those who engage in the practice of the profession. The "practice of pharmacy" is defined by § 40-43-30(44) as follows:

> (44) "Practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, prospective drug reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmacy care and drug therapy management; and responsibility for compounding and labeling of drugs and devices, (except labeling by a manufacturer, repackager, or distributor or nonprescription drugs and commercially packaged legend drugs and devices) proper and safe storage of drugs and devices and maintenance of proper records for them; or the offering or performing of those acts, services, operations, or transactions necessary in the conduct, operation, education, management, and control of pharmacy.

The term "pharmacy care" is defined by § 40-43-30(38) as the following:

> "Pharmacy care" is the direct provision of drug therapy and other pharmacy patient care services through which pharmacists, in cooperation with the patient and other health care providers, design, implement, monitor, and manage therapeutic plans for the purpose of improving a patient's quality of life. Objectives include care of disease, elimination or reduction of a patient's symptomatology, arresting or slowing a disease process, or prevention of a disease or symptomatology, The process includes three primary functions:
>
> (a) identifying potential and actual drug-related problems;
> (b) resolving actual drug-related problems; and
> (c) preventing potential drug-related problems.

Section 40-43-30(39) defines a "pharmacist" as "an individual health care provider licensed by this State to engage in the practice of pharmacy. A pharmacist is a learned professional authorized to provide patient care services within the scope of his knowledge and skills."

In addition, a pharmacist is authorized to provide limited counseling to patients to which the pharmacist provides pharmaceutical services. See, § 40-43-86(L)(1). Subsection (L)(1) provides that

> [u]pon receipt of a prescription drug order for a new medication and following review of the patient's pharmacy record, the pharmacist shall personally offer counseling to the patient or the patient's agent. Using his best professional judgement, the pharmacist's counseling shall include a discussion of those matters

> that the pharmacist considers appropriate for the patient or patient's agent in that particular situation.
>
> The discussion must be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling. The elements may include:
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> (a) the name and description of the drug;
> (b) the dosage form, dose, route of administration, and duration of drug therapy;
> (c) intended use of the drug and expected action;
> (d) special directions and precautions for preparation, administration, and use by the patient;
> (e) potentially serious side effects or interactions, and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
> (f) techniques for self-monitoring drug therapy;
> (g) proper storage;
> (h) prescription refill information;
> (i) action to be taken in the event of a missed dose; and
> (j) pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

Section 40-43-30(18) defines "drug therapy management." "Drug therapy management" is "that practice of pharmacy which involves the expertise of the pharmacist in a collaborative effort with the practitioner and other health care providers to ensure that the highest quality health care services for patients." A "pharmacy" is defined by § 40-43-30(41) as

> ... a location for which a pharmacy permit is required and in which prescription drugs and devices are maintained, compounded, and dispensed for patients by a pharmacist. This definition includes a location where pharmacy-related services are provided by a pharmacist.

Section 40-47-5 et seq. regulates the practice of medicine. The "practice of medicine" is defined by § 40-47-40 as the following:

> [a]ny person shall be regarded as practicing medicine within the meaning of this article who (a) shall as a business treat, operate on or prescribe for any physical ailment of another, (b) shall engage in any branch or specialty of the healing art or (c) shall diagnose, cure, relieve in any degree or profess or attempt to diagnose, cure or relieve any human disease, ailment, defect, abnormality or complaint, whether of physical or mental origin, by attendance or advice, by prescribing, using or furnishing

> any drug, appliance, manipulation, adjustment or method or by any therapeutic agent whatsoever.

As the past president of the S.C.M.A. physician states in his letter, current federal regulations on clinical laboratory testing, promulgated by the Department of Health and Human Services pursuant to the Clinical Laboratory Improvement Act of 1988 (CLIA) shed light on this issue. In response to growing public concern about the quality of clinical laboratory testing, Congress passed CLIA in 1988 to ensure competence among laboratories testing human specimens for disease diagnosis, prevention, monitoring, and treatment." Consumer Federation of America and Public Citizen v. U.S. Dept. of Health and Human Services, 83 F.3d 1497, 1499 (D.C. Cir. 1996). 42 U.S.C.A. § 263a establishes three categories of medical laboratory testing, based upon the level of complexity involved in the performance and evaluation of the test. The lowest level of testing, designated as "waived tests" include those tests "which are so simple to perform that the likelihood of an erroneous test is extremely small." Id. at 1502. In order to conduct these "waived tests," the testing facility is required to obtain a "Certificate of Waiver" from the Centers for Medicare and Medicaid Services (CMMS), a division of the Department of Health and Human Services. 42 U.S.C. § 263a(b), § 263a(d)(2); 42 C.F.R. § 493.15. Consistent with § 263a(d)(3) of the Act, CMMS has established general criteria for what constitutes a "waived" test in 42 C.F.R. 493.15(b). Such provision states:

> Test systems are simple laboratory examinations and procedures which –
>
> (1) Are cleared by FDA for home use;
> (2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
> (3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

Section 493.15(d) of the CMMS regulations states that "HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this Section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the Federal Register in a notice with opportunity for comment."

It is our understanding that at least some simple cholesterol monitoring tests have now been classified as "waived tests." If a particular cholesterol monitoring test is in fact a "waived test," federal law would permit a pharmacist to administer this test if he obtains a Certificate of Waiver from CMMS.

However, federal law does not end the inquiry. It is recognized that "[f]acilities performing only waived tests must follow accepted laboratory practices and comply with other relevant federal, state and local requirements ..." Consumer Federation of America, supra at 1502. Accordingly, we

must determine whether South Carolina law – the Pharmacy Practice Act and the Medical Practice Act – permit a pharmacist to conduct simple cholesterol tests.

This Office has, on a number of occasions, addressed the interrelationship of these two acts in the context of certain factual situations. For example, in an opinion dated September 24, 1973, we noted that the Pharmacy Practice Act "specifically exempts from the Medical Practice Act the selling, using an dispensing of drugs by licensed pharmacists while in their places of business." In Op. S.C. Atty. Gen., Op. No. 4408 (July 29, 1976), we concluded that "the substitution of a different brand of the same generic drug amounts to the prescription of a drug and, thus, the practice of medicine." Thus, such substitution could not be performed by a pharmacist but only by a licensed physician. In that opinion, we noted that the Medical Practice Act excludes from its prohibition against the unauthorized practice of medicine only the 'selling, using and dispensing' of drugs by a licensed pharmacists." By contrast, in Op. S.C. Atty. Gen., Op. No. 4498 (October 20, 1976), we distinguished a situation where the physician prescribes a drug product generically without designating a particular brand name. In that situation, we noted the "physician has, in effect, made the medical judgment that all of the available brands are therapeutically equivalent and, thus, the pharmacist may choose the specific brand of drug product prescribed just as he chooses the specific drug lot or, indeed, the specific container from which the prescription is to be filled."

In another opinion, dated November 30, 1964, we concluded that a "health center" which would check a client's blood pressure, pulse rate, rate of respiration and temperature for a charge involved the practice of medicine. We cited a Minnesota Supreme Court decision, Granger v. Adson, 250 N.W. 722 (1933), which held that a layman furnishing for a fee to subscribers the results of urinalysis and blood pressure tests and either himself advising or passing on to subscribers advice from a pathologist was engaged in the unlawful practice of medicine. It was our conclusion that

> ... one who owns and operates a health center which performs hemoglobin determinations, blood counts, or other laboratory tests with the intention of diagnosing human disease and without the supervision of a licensed pathologist, would be engaged in the unlawful practice of medicine ... .

This same conclusion was reached in an earlier opinion, dated July 18, 1961 (Op. No. 1154).

Moreover, an opinion dated March 3, 1981 concluded that the performance of a needle muscle biopsy procedure constituted the practice of medicine. In that opinion, we noted that "several jurisdictions have long held the 'penetration of the skin' to be a surgical operation." We cited cases such as Kelley v. Raguskas, 270 N.W.2d (Mich. 1978) which held that acupuncture constituted the practice of medicine as well as People v. Bouce, 285 N.W.2d 53 (Mich. 1980), which concluded that the drawing of blood involved the practice of medicine.

Furthermore, the Louisiana Attorney General has concluded that the preventative screening by Med-Screen Company with ultra sound technology for cardiovascular disease constitutes the

practice of medicine. The Louisiana Attorney General cited Baque v. Pan-American Life Insurance Company, 313 So.2d 293 (La. App. 3 Cr. 1975) for the proposition the examinations, diagnostic studies and treatment are "reasonably necessary to determine the cause, nature and extent" of a particular disease. While it was not clear that Med-Screen was performing examinations. In the view of the Louisiana Attorney General "the testing for evidence of disease" falls within the practice of medicine.

An opinion by the Attorney General of Delaware, rendered on May 6, 1996 (Op. No. 96-IB14) is analogous to the situation here. There, the question was whether pharmacists possess the authority "to draw blood for glucose monitoring and give immunizations." The Attorney General concluded that "the drawing of blood for glucose monitoring and giving immunizations is not within a pharmacist's practice ...."

The Delaware statutory definition of "practice of pharmacy" is similar to the definition found in the South Carolina Code at § 40-43-30(44), referenced above. In concluding that the administration of cholesterol tests by pharmacists did not fall within the "practice of pharmacy," the Attorney General of Delaware stated the following:

> [t]he practice of pharmacy as legislated in Delaware clearly focuses on the application of pharmaceutical science which is authorized by a prescriber's order. The services of the pharmacist are performed within the license of the "practice of pharmacy." Drawing blood for glucose testing and giving immunizations are not within the application of pharmaceutical science because such testing requires that the patient's skin be broken by a finger stick procedure to draw blood to complete the test. Likewise immunizations (other than oral vaccines) are given by shot therapy which requires an intramuscular injection. Neither procedure comes within the scope of activity by which pharmacists are licensed ... .
>
> Accordingly, we conclude that pharmacists may not draw blood for glucose monitoring nor give immunizations by injection.

Conclusion

As noted above, we have found no decision from this State or from any other jurisdiction directly on point with respect to your question. However, the authorities cited above suggest that the Pharmacy Practice Act does not authorize the administration of the cholesterol test in question. As stated in our earlier opinion of July 29, 1976, the basic thrust of a pharmacist's practice is the "selling, using and dispensing of drugs." Thus, it is doubtful whether the administration of a cholesterol test by a pharmacist is encompassed within the pharmacist's scope of practice. Although the Pharmacy Practice Act contains provisions which arguably might be deemed to support such authorization, we believe the better interpretation is otherwise. Section 40-43-30(41) does not attempt to define "pharmacy-related services" as including the administration of cholesterol tests.

Moreover, there is no indication that the "collaborative effort with the practitioner and other health care providers to ensure the highest quality health care services for patients" include the administration of such tests. See, § 40-43-30(18). See also, § 40-43-30(38) ["other pharmacy patient care services"]. Absent more specific authorization contained in the Pharmacy Practice Act, we cannot conclude such authorization is present in current law. More likely, a court would deem the performance of such tests by a pharmacist to be the unauthorized "practice of medicine."

A previous opinion of this Office recognized that a declaratory judgment action pursuant to § 15-13-10 et seq. of the Code is the only definitive means by which to resolve the question of whether certain activities constitute the practice of medicine. See, Op. S.C. Atty. Gen., October 23, 1979; § 15-53-10 et seq. of the Code. Such an action could be brought with respect to the administration of these cholesterol tests by pharmacists in order to determine with certainty whether such tests can or cannot be performed. Moreover, the General Assembly could address this question by way of statutory clarification.

Absent a ruling by a court or legislative amendment, we doubt whether the administration of cholesterol tests by pharmacists is currently authorized under state law.

Very truly yours,

Robert D. Cook
Assistant Deputy Attorney General

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