

August 26, 1997

James G. Eberz, Esq.
Meiselman, Farber, Packman & Eberz, P.C.
118 Bedford Road
P.O. Box 151
Mt. Kisco, New York 10549

Dear Mr. Eberz:

I am responding to your April 22, 1997 letter to MaryAnne Kowalski. You are asking two questions which are set forth and answered below.

Question 1

May the owner of a clinical laboratory enter into an employment contract with a New York medical professional corporation to act as director of the laboratory? Please assume that one of the owners of the professional corporation is qualified and could individually act as director.

Answer

No. A medical professional corporation (P.C.) may not act as the laboratory director of a clinical laboratory because the laboratory director must hold a certificate of qualification which may only be issued to an individual.

Question 2

May the owner of a clinical laboratory enter into a services agreement with a New York medical professional corporation to provide all professional and technical services, including employment of the necessary pathologists and

technologists, relative to the operation of the laboratory?

Answer

Yes, as long as the laboratory ensures that the services provided pursuant to the agreement meet the applicable requirements of 10 NYCRR Subpart 58-1.

Discussion

For purposes of this discussion, we assume that the relationships entered into between the clinical laboratory and the medical P.C. do not result in violations of the requirements and limitations of Business Corporations Law (BCL) Article 15, or to violations of the prohibition against the corporate practice of medicine. If there are unresolved issues related to BCL Article 15 or to the corporate practice prohibition, the State Education Department, which has jurisdiction over issues regarding the scope of practice of medicine, should be consulted.

Under Public Health Law (PHL) §§ 572, 573, 10 NYCRR Part 19 and 10 NYCRR §§ 58-1.1(a)(1) and 58-1.2, the laboratory director of a clinical laboratory must hold a certificate of qualification (C of Q) issued by the Department of Health (department) based on standards set by the Public Health Council (PHC). The C of Q is issued to an individual who is held accountable in accordance with the cited statutes and regulations. The C of Q cannot be issued to a corporation, including a medical P.C., for the same reasons that any license must be issued to an individual and not a corporate entity. It is the individual who qualifies for the license and is granted the accompanying privileges and responsibilities.

BCL Article 15, which gives a medical P.C. the legal authority to practice medicine without violating the prohibition against the corporate practice of that profession, does not alter this conclusion. Since a certificate of qualification is required in order to be a laboratory director even if the prospective director is a licensed physician, the scope of practice of laboratory directorship is different from that of medicine.¹ A physician may not, by virtue of his/her medical

¹ Our conclusion is supported by Derman v Ingraham, 47 Misc.2d 346 (Ulster Co. 1965), aff'd, 25 A.D.2d 795 (3rd Dept. 1966), lv denied, 18 N.Y.2d 579 (1966). In Derman, pathologists claimed that they were being denied equal protection of the laws because, unlike other physicians, they were required to have a

license, be a laboratory director, and a laboratory director, absent a license to practice medicine, may not be a physician. Therefore, although a medical P.C. is authorized by BCL Article 15 to practice medicine, Article 15 is not authorization for a medical P.C. to act as a laboratory director.

Neither is this conclusion altered by the fact that one of the owners of the P.C. holds a C of Q. Neither the PHL nor its implementing regulations provides that ownership of a medical P.C. by a C of Q holder confers on the P.C. the authority to act as a laboratory director.

There is no express or implied prohibition in the PHL or its implementing regulations against a clinical laboratory entering into a contractual arrangement with a medical P.C. pursuant to which the P.C. provides professional and technical services which fall within the scope of practice of medicine, to the laboratory. Your facts are unclear as to whether, under the

physician's license as well as meet the requirements for a certificate of qualification in order to carry out their profession. Once PHL article 5 title V mandated licensure for clinical laboratories, and that the laboratory director hold a certificate of qualification, pathologists examining tissue specimens sent to them from other physicians, and providing diagnostic information back to the referring physician, had to obtain a laboratory permit for their office facility and, if the pathologist functioned as the laboratory director, also had to obtain a certificate of qualification. The pathologists argued that their medical license should be sufficient to allow them to examine specimens and convey diagnostic information. Implicit in this argument was the assumption that the certificate of qualification was subsumed within the medical license so that the physician should be allowed to function as a laboratory director without a certificate. The court rejected this argument and upheld the requirement that the pathologist hold a certificate of qualification as well as a medical license. The court found the medical license alone insufficient, stating:

The Legislature could reasonably conclude that the qualifications which one must possess to practice medicine, including the specialty of pathology...are somewhat different than those necessary to insure the proper direction of a clinical laboratory.

Derman, 47 Misc 2d. at 349.

contractual arrangement contemplated by question 2 above, the employer would be the laboratory or the medical P.C., but in either case, a clinical laboratory could contract with a medical P.C. to provide the services of technicians and other professionals as long as those services fall within the scope of practice of medicine. In order to clarify whether such services fall within the scope of practice of medicine and are permitted under article 15 of the BCL, you should contact the Education Department, which has jurisdiction over the scope of practice of medicine issues. It would be the responsibility of the laboratory to ensure that all services provided pursuant to the contractual arrangement are consistent with and do not result in violations of the applicable provisions of PHL article 5 title V and 10 NYCRR Subpart 58-1.

The remaining issue is whether the medical P.C., although unable to act as a laboratory director, may enter into a contractual relationship with the laboratory pursuant to which the director is provided by the P.C. The department would have no objection to such an arrangement, with the proviso that the director would have to be employed by the laboratory [see 10 NYCRR § 58-1.2(e),(f)], and the director and the laboratory would be held responsible for ensuring compliance with all applicable provisions of PHL Article 5 Title V and 10 NYCRR Part 19 and Subpart 58-1. In addition, the State Education Department should be consulted to determine if a medical P.C. may enter into such a relationship.

I suggest that, in relation to the issues you raise, you consult PHL article 2 title II-D which prohibits a practitioner from making referrals for clinical laboratory services, to a laboratory with which the practitioner has a financial relationship. Under your facts the medical P.C. and clinical laboratory would have a financial relationship which prohibits referrals from the P.C. to the laboratory.

Sincerely,

Harriet S. Bougen
Senior Attorney

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