



STATE OF NEW YORK DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Executive Deputy Commissioner

December 1, 2008

Peter Millock, Esq.
Nixon Peabody LLP
677 Broadway – 10th Floor
Albany, New York 12207

Dear Mr. Millock:

Your letter of July 21, 2008, requested a legal opinion from this office. Specifically, you asked about a potential arrangement where a clinical laboratory would perform certain laboratory technical and management services for a physician private practice (the practice) in New York.

Your letter inquires about the following fact pattern. There is a laboratory in the practice that purports to be a physician's office laboratory (POL), with the clinical laboratory providing certain laboratory management services. An employee of the clinical laboratory, such as a histotechnologist, performs the technical component of certain anatomic pathology services in space provided by the practice. The employee of the clinical laboratory assists the practice in performing slide preparation from specimens collected by the practice from some type of physician examination or physician collection procedure. After the slide preparation is completed by the employee of the clinical laboratory, the slide would be provided to the practice for performance of the professional interpretation and issuance of the test report. Additionally, as a part of the management of the laboratory in the practice, the clinical laboratory provides equipment and related supplies necessary for the operation of the laboratory in the practice. The practice would provide the space, utilities, maintenance, waste disposal, billing and collections, quality assurance, licensure, medical directorship and operational oversight of the laboratory in the practice. Your question is whether the onsite supportive service is acceptable if the clinical laboratory is compensated at fair market value for the services and materials provided to the practice.


The arrangement as described in your letter is not acceptable to the Department. Although you do not raise this issue in your letter, the laboratory in the practice would not qualify as a POL under Public Health Law (PHL) § 579(1), because the laboratory in the practice is not "operated by" the physician "personally or through his or her employees." Rather, according to the facts provided, the clinical laboratory is providing "laboratory management services" and would "provide equipment and related supplies

necessary for the operation of the [laboratory in the practice]." Moreover, "the clinical laboratory . . . would perform the technical component" of laboratory services, and "slide preparation is completed by the [clinical] laboratory," not the practice. Therefore, the laboratory in the practice is not operated by the practice and would require a permit under PHL Article 5, Title V.

If the laboratory in the practice were under permit, the business arrangement would need to be structured to comply with PHL Article 2, Title II-D and PHL § 586. More facts would be needed to determine whether this arrangement would comply with those laws. For your information, I attach two general counsel opinions addressing these issues dated April 30, 1996, and June 7, 1996.

Since the laboratory in the practice would not be a POL, there is no need to address your question regarding whether the arrangement would violate PHL § 587 and 10 NYCRR § 34-2.7.

Very truly yours,


Thomas Conway
General Counsel

Enclosures

