November 21, 1995

Barbara A. Ryan, Esq.
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Dear Ms. Ryan:

I am responding to your letter dated August 28, 1995. You ask whether it is permissible for three physicians with separate medical practices to share a clinical laboratory, or whether such an arrangement would violate the Health Care Practitioner Referrals Act codified at Public Health Law (PHL) Article 2, Title II-D, sections 238 through 238-c. The arrangement you describe is not permissible.

Facts:

The following facts were stated in your August 28 letter or during subsequent phone conversations with me. You describe three physicians, two of whom are solo practitioners and the third is the sole shareholder in a medical professional corporation. They own and share a suite of offices located in a cooperatively owned building in New York City. Each medical practice has a separate practice area, secretary, receptionist and waiting area. The visiting hours overlap, although they are not identical. There is a clinical laboratory located in the shared suite of offices in an area that is entirely separate from any of the physician's practices. You state that the "lab services include blood work, x-rays, radio-iodine testing, and pulmonary function tests." This definition deviates from the statutory definition of a clinical laboratory set forth at PHL §574 and the definition of clinical laboratory services set forth at PHL §238(1). To avoid confusion, all references in this letter to clinical laboratory or clinical laboratory services means the definitions in the cited statutes.

The equipment used in the clinical laboratory and to

provide x-ray, radio-iodine testing and pulmonary function tests is jointly owned by the three medical practices. The equipment is serviced by a company jointly paid by the practices. Calibration and daily maintenance is by the technician operating the equipment. The clinical laboratory technician is paid jointly by the three medical practices, each practice paying for a third of the joint employee's time independent of how long the employee spends on a particular physician's referrals. There is a similar arrangement for the x-ray and other technicians. When clinical laboratory, x-ray or other services are performed for a particular physician's patient, the technician performing the services is considered to be under the supervision of the referring physician. However, this does not mean that the physician is present in the suite when the services are performed or is otherwise available; it means that the technician is working under the auspices of the ordering physician. The clinical laboratory had a New York City permit and has applied for a New York State permit under PHL Article 5, Title V.

Discussion:

PHL §238-a prohibits a physician from making referrals for certain designated services if the physician has a financial relationship with the provider. The designated services are clinical laboratory, x-ray and imaging, and pharmacy services. Financial relationship is given a broad definition at PHL §§238(3), 238-a(3),(4),(5). The reason for the prohibition is to ensure that physicians order tests and select laboratories, x-ray and imaging facilities and pharmacy services based on medical necessity, quality of services and the patient's best interests, and not on the physician's financial investment. A physician sharing a clinical laboratory or facilities which provide pharmacy or x-ray or imaging, is financially interested in the equipment, lease, or employees and so is prohibited from referring to the shared facility. Under the facts you describe, the physicians are sharing employees, equipment and space, and are prohibited by PHL §238-a(1)(a) from referring their patients to the shared facility for clinical laboratory, x-ray or imaging, or pharmacy services.

Shared facilities do not fit any exception to the self-referral ban, and in particular do not fit the exception for in-office ancillary services set forth at PHL §238-a(2)(b). If we determined that the in-office ancillary services exception applied, then it would be possible for an unlimited number of doctors to share a facility for clinical laboratory, x-ray or imaging, or pharmacy services, and refer their patients to that shared facility and so circumvent the law. Physicians have

several options. They can have their own clinical laboratory, or form a group practice meeting the in-office ancillary services exception.

You may want to review the federal self-referral ban codified at 42 USC §1395nn (Stark II), and the regulations promulgated to implement Stark I, pertaining only to clinical laboratory services, published at 60 FR 41914. Although there is no separate federal exception for shared laboratories, you may want to consult with the Health Care Financing Administration (HCFA) which implements the federal statute, to ask that agency's opinion on the arrangement you have described.

Sincerely,

Harriet B. Oliver
Senior Attorney