

August 7, 1996

Cynthia D. Shenker, Esq.
Wilson, Elser, Moskowitz, Edelman & Dicker
One Steuben Place
Albany, NY 12207

Dear Ms. Shenker:

I write in response to your letter of July 26, 1996 requesting confirmation that the proposed revised arrangements by your client, Northern Litho, and urologists for the provision of lithotripsy services would not require a Certificate of Need ("CON") application.

As noted in your letter, Northern Litho proposes to bring a mobile lithotripsy unit to the Buffalo area and alternately locate it on the grounds of two Buffalo hospitals. The significant features of the arrangement include:

1. The unit would not be located within the confines of the two hospitals, but would be located in a parking area or other similar location on the grounds of the hospital. Northern Litho and the hospital would enter into a lease agreement with hospitals for the fair market value of the space provided, which would serve as the sole financial arrangement between Northern Litho and the hospitals.
2. The hospital will not bill for the procedure or the provision of any services provided in the mobile

unit, and will not share in any profits or percentage of the revenue associated with the operation of the mobile unit or the services provided therein other than scheduled rent payments of a fixed amount.

3. The lithotripsy service will not be represented as being operated by the hospitals. The hospitals will not be involved in any aspect of the operation of the mobile unit or the services provided therein, including, but not limited to, patient scheduling, the provision or supervision of the mobile unit's staff or services provided within the mobile unit, the maintenance of equipment, and ordering of supplies.
4. The lithotripsy procedure will be performed directly by area urologists. The urologists will have no financial interest in Northern Litho. The only reimbursement or financial consideration provided to the urologist is the standard professional fee which they will receive for performing the procedure directly from third party payors.
5. Northern Litho will not employ or contract with, any doctor to act as a "medical director". Additionally, Northern Litho will not employ any doctor and there will not be any independent contractor relationships between Northern Litho and area urologists.
6. Scheduling will not be done directly between the patient and Northern Litho. The need for lithotripsy services will be

determined by a urologist in either a private practice or hospital setting and the physician will make the patient appointment and arrangements with Northern Litho for access to the mobile unit.

7. The urologists performing the lithotripsy procedure will bill third parties directly for their professional services. The urologists will not be employees of Northern Litho. Northern Litho will bill the patient or third parties for the technical services provided by Northern Litho. The "technical services" which will not involve any activity which requires a medical or other professional license.

Based upon the description of the proposed arrangements set forth in your letter and restated above, it does not appear that either the hospitals or Northern Litho are required to submit a CON application. As described, the services performed by Northern Litho amount only to the provision of space, equipment and non-professional services, which in and of themselves do not require a medical or other professional license or supervision by a medical licensee. As such, Northern Litho is not providing services by or under the supervision of a physician as anticipated by the definition of a "hospital" in Public Health Law § 2801(1). All medical services will be provided directly by independent urologists who will not be employed or supervised by Northern Litho. Additionally, since the patients will be the patients of the urologists and all services will be performed by the urologists, Northern Litho does not appear to be arranging for the provision of physician services which would violate the prohibition against the corporate practice of medicine and require licensure as a diagnostic and treatment center. However, the department is unable to render any definitive opinion in this regard without reviewing the specifics of any contract between Northern Litho, and the hospitals in light of the criteria set forth in 10 N.Y.C.R.R. § 600.8, and the prohibitions against fee splitting, the corporate practice of medicine doctrine, referrals for a fee and other related statutes.

Of particular concern is that such agreements may make the urologists "agents" of Northern Litho, create some obligation

for the urologists to provide services or referrals to Northern Litho, establish questionable compensation arrangements, permit Northern Litho or the hospitals to specify the manner of care by the physicians utilizing the premises, or give Northern Litho any direction or control over the provision of medical services. Although nothing in your letter concerning the proposed arrangements raises specific concerns with regard to these issues, this office has provided you with copies of numerous opinions and case cites which address the legalities of various arrangements between physicians and non-professionals, including fee-splitting, referral for a fee, undue influence, medical referral services, the corporate practice of medicine and the bar against physician self-referral. In particular, the opinion letters should provide you with ample guidance to draft agreements between your client and the hospitals and urologists without violating these prohibitions. We also note that the proposed arrangement does not violate Public Health Law Article 2, Title II-D because it does not involve the provision of clinical laboratory services, pharmacy services or x-ray or imaging services. But the arrangement would raise concerns regarding this statute if it involved the provision of such services as indicated in the opinion letters provided.

As for the role of the hospitals, it appears that they will act solely in the capacity of landlord of Northern Litho and will not be involved in providing, supervising or arranging for the services within the mobile unit. Patients utilizing the unit will be urologists' patients generally. The unit will be operated as a unit separate and distinct from the hospitals, and the hospitals will not receive compensation based upon the revenues or profit of the unit. Accordingly, the hospitals would not be considered the operators or owners of the unit and the services provided therein, nor would they be required to obtain a CON approval before permitting such services to be located on land owned by the hospitals.

In light of the foregoing, the operation of Northern Litho does not appear to constitute the operation of a diagnostic and treatment center or require the submission of a CON application. However, care must be taken in the drafting of all agreements and in the provision of services to ensure compliance with the specifics set forth in your letter and the opinion letters provided.

Sincerely,

-5-

Henry M. Greenberg
General Counsel

HMG/JLD/vg