NORTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF HEALTH SERVICE REGULATION
RALEIGH, NORTH CAROLINA

IN RE: REQUEST FOR DECLARATORY RULING BY HOPE-A WOMEN'S CANCER CENTER, PA	**)** **)** **)**	**DECLARATORY RULING**

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Hope-A Women's Cancer Center, PA ("Hope") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. Hope has filed a Declaratory Ruling Request (the "Request") asking the Department to issue a ruling as to the applicability of N.C.G.S. Chapter 131E, Article 9 to the facts described below. For the reasons given below, I must deny Hope's Request.

This ruling is binding on the Department and the person requesting it if the material facts stated in the Request are accurate and no material facts have been omitted from the request. The ruling applies only to this request. Except as provided by N.C.G.S. § 150B-4, the Department reserves the right to change the conclusions which are contained in this ruling. Noah H. Huffstetler, III and Denise M. Gunter of Nelson Mullins Riley & Scarborough, LLP, counsel for Hope, have requested this ruling on behalf of Hope and have provided the statement of facts upon which this ruling is based.

In addition, comments on the Request have been received from the following:

(1) Robert V. Bode of Bode, Call & Stroupe, L.L.P., on behalf of the North Carolina Hospital Association, Central Carolina Hospital, Hugh Chatham Memorial Hospital, Frye Regional Medical Center, and Southeast Radiation Oncology Group, P.A.

(2) Forrest W. Campbell, Jr., of Brooks, Pierce, McLendon, Humphrey & Leonard, L.L.P., on behalf of Onslow Memorial Hospital.

(3) Terrill Johnson Harris of Smith Moore LLP on behalf of Mission Hospitals, WakeMed and Margaret R. Pardee Memorial Hospital.

(4) Frank S. Kirschbaum of Kirschbaum, Nanney, Keenan & Griffin, P.A., on behalf of Asheville Radiology Associates, P.A.

(5) Gary S. Qualls, Colleen M. Crowley, and William W. Stewart, Jr., of Kennedy Covington Lobdell & Hickman, L.L.P., on behalf of Charlotte-Mecklenburg Hospital Authority d/b/a/ Carolinas HealthCare System, Cumberland County Hospital System, Inc., d/b/a Cape Fear Valley Health System, High Point Regional Health System and Rex Hospital, Inc.

All of these commenting parties (collectively "Commentators") opposed the Request.

The material facts as provided by counsel for Hope are set out below.

STATEMENT OF THE FACTS

Hope states that it operates a health service facility as defined in N.C. Gen. Stat. § 131E-176(9b) (the "Facility") located at 100 Ridgefield Court, Asheville, North Carolina 28806. By a CON dated 13 July 2005, in Project I.D. No. B-7047-04, Hope was authorized to "[a]cquire a mammography unit, stereotactic breast biopsy unit, bone densitometry unit, and x-ray equipment resulting in the establishment of a diagnostic center and an oncology treatment center [in] Buncombe County." At the Facility, Hope currently offers radiology services including mammography, bone densitometry, x-ray, ultrasound, and stereotactic biopsy, as well as chemotherapy services

In the Request, Hope states that it intends to enter into a Services Agreement with an out-of-state business corporation (the "Provider"). Pursuant to this Services Agreement, the Provider

will furnish to Hope diagnostic and radiation oncology services for Hope's patients. Those services will be provided using the equipment described below (the "Equipment") which will be acquired by the Provider outside of North Carolina and will continue to be owned by the Provider. The Equipment to be made available under the Services Agreement will include a linear accelerator with a multi-leaf collimator, a dual use positron emission tomography ("PET") scanner with computerized tomography ("CT") capability (which will be used for both diagnostic and treatment simulation purposes), and a magnetic resonance imaging ("MRI") scanner. In addition to the use of the Equipment, the Provider will furnish certain personnel, ancillary equipment, disposable supplies, maintenance services and technical support necessary to the functioning of the Equipment.

Hope represents that under the Services Agreement, the Provider will retain the risk of any loss or damage to the Equipment, and will be responsible for its insurance. The Provider will be liable for any property or other taxes on the Equipment. No specifically identified unit of the Equipment will be required to be furnished under the Services Agreement. So long as the Equipment meets the specifications set forth in the Services Agreement, the Provider will have the option to select the particular units of the Equipment to be used, and substitute units of the Equipment as may become necessary. Hope will not purchase, lease or otherwise acquire any ownership or property interest in the Equipment.

Hope states that the Equipment will be installed in an expansion of the Facility. The Equipment will be installed in the Facility and will be utilized only at that location. Upon termination of the Services Agreement, Hope represents that the Equipment will be removed from the Facility and will be disposed of in accordance with any provisions of law then in effect.

Hope attached as an exhibit to the Request the affidavit of Michael A. Crawford, a certified public accountant licensed to practice in North Carolina. Mr. Crawford avers that the compensation to be paid by Hope to the Provider under the Services Agreement would be characterized as an expense of operation and maintenance, and not a capital expenditure, under generally accepted accounting principles.

Hope attached as an exhibit to the Request a certified estimate of the capital costs that will be incurred by Hope in connection with the proposed transaction, prepared by Christopher S. Goodwin, AIA, an architect licensed to practice in North Carolina. This certified estimate purports to include a detailed itemization of all of Hope's anticipated capital costs which are necessary to make the Equipment operational, totaling $1,946,052. Mr. Goodwin's affidavit does not include the cost or fair market value of the Equipment.

Hope did not identify the Provider in the Request, nor did it submit a copy of the proposed Services Agreement.

Hope requests a determination that the transaction described in the Request and its subsequent provision of services to patients as described does not constitute a new institutional health service pursuant to N.C.G.S. § 131E-176(16), and that Hope is not required to obtain a CON for the described transaction.

ANALYSIS

The Request implicates several provisions of the CON law, N.C.G.S. Chapter 131E, Article 9.

First, as to the general purpose and intent of the law as it relates to the facts set forth in the Request, the General Assembly made the following findings of fact:

> 4) That the *proliferation of unnecessary health service* facilities results in costly duplication and underuse of facilities, with the availability of

> *excess capacity* leading to unnecessary use of expensive resources and overutilization of health care services.
>
> . . . . .
>
> 6) That *excess capacity of health service facilities* places an enormous economic burden on the public who pay for the construction and operation of these facilities as patients, health insurance subscribers, health plan contributors, and taxpayers.
>
> (7) That the general welfare and protection of lives, health, and property of the people of this State *require that new institutional health services to be offered within this State be subject to review and evaluation as to need, cost of service, accessibility to services, quality of care, feasibility, and other criteria* as determined by provisions of this Article or by the North Carolina Department of Health and Human Services pursuant to provisions of this Article prior to such services being offered or developed *in order that only appropriate and needed institutional health services are made available* in the area to be served.

N.C.G.S. § 131E-175 (emphasis added).

The CON law implements the General Assembly's findings by providing: "No person shall offer or develop a new institutional health service without first obtaining a certificate of need from the Department . . . " N.C.G.S. § 131E-178(a). It further provides:

> No person shall make an acquisition by donation, lease, transfer, or comparable arrangement without first obtaining a certificate of need from the Department, if the acquisition would have been a new institutional health service if it had been made by purchase. In determining whether an acquisition would have been a new institutional health service, the capital expenditure for the asset shall be deemed to be the fair market value of the asset or the cost of the asset, whichever is greater.

N.C.G.S. § 131E-178(b).

"Person" is broadly defined as "an individual, a trust or estate, a partnership, a corporation, including associations, joint stock companies, and insurance companies; the State, or a political subdivision or agency or instrumentality of the State." N.C.G.S. § 131E-176(19). "To 'offer,' when used in connection with health services, means that the person holds himself

out as capable of providing, or as having the means for the provision of, specified health services." N.C.G.S. § 131E-176(18). "To 'develop' when used in connection with health services, means to undertake those activities which will result in the offering of institutional health service or the incurring of a financial obligation in relation to the offering of such a service." N.C.G.S. § 131E-176(18).

The definition of "person" clearly encompasses Hope, and, although Hope does not identify the Provider, the definition almost certainly encompasses the Provider. The transaction described by Hope clearly involves either Hope or the Provider holding themselves out as capable of providing, or having the means for the provision of health services (i.e., "offering), and it describes the activities that Hope and the Provider will undertake to result in the offering of the services described. In the transaction described in the Request, therefore, Hope and the Provider, either individually or collectively, are persons offering or developing the described service.

The question then becomes whether the transaction constitutes a "new institutional health service." Several elements of the definition of "new institutional health service" in N.C.G.S § 131E-176(16) apply.

1. **Acquisition of equipment**

The acquisition by purchase, donation, lease, transfer, or comparable arrangement of certain equipment, by or on behalf of any person, is by definition a new institutional health service. N.C.G.S. § 131E-176(16)f1. The following items of equipment listed by Hope in the Request are included in the definition: Linear accelerator, Magnetic resonance imaging scanner, Positron emission tomography scanner, and Simulator. The acquisition of any of these pieces of

equipment to be offered or developed in North Carolina by either Hope or the Provider, therefore, is subject to the requirement for a CON.

Hope argues that the transaction it describes is not an "acquisition" or "comparable arrangement" for purposes of the statutory definition. Its rationale appears to be that it would not be taking title or other form of ownership of the equipment. In the absence of the Services Agreement, it is not possible to determine exactly what the legal relationship is between Hope, the Provider and the Equipment. However, Hope clearly proposes to put into operation at the Facility in North Carolina equipment that has not been in service in North Carolina, and that the Equipment will be or will have been acquired by either Hope or the Provider. Further, Hope or the Provider, or perhaps both, propose to hold themselves out as offering the services of the Equipment. Acquiring the ability to provide services using the Equipment in the State of North Carolina pursuant to some arrangement with an out-of-state Provider, regardless of how it is labeled or packaged, is a comparable arrangement under N.C.G.S. §§ 131E-176(16)f1 and 131E-178(b). This conclusion is supported by the Findings of Fact of the General Assembly recited above.

The proposed transaction, therefore, constitutes the acquisition by comparable arrangement of equipment that is a new institutional health service and that requires a CON.

2. **Capital Expenditure in excess of $2,000,000**

Another category of "new institutional health service" is defined as follows:

> The obligation by any person of a capital expenditure exceeding two million dollars ($ 2,000,000) to develop or expand a health service or a health service facility, or which relates to the provision of a health service. The cost of any studies, surveys, designs, plans, working drawings, specifications, and other activities, including staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement of any plant or equipment with respect to which an

> expenditure is made shall be included in determining if the expenditure exceeds two million dollars ($ 2,000,000).

N.C.G.S. § 131E-176(16)b.

"Capital expenditure" is defined as:

> an expenditure for a project, including but not limited to the cost of construction, engineering, and equipment which under generally accepted accounting principles is not properly chargeable as an expense of operation and maintenance. *Capital expenditure includes, in addition, the fair market value of an acquisition made by donation, lease, or comparable arrangement by which a person obtains equipment, the expenditure for which would have been considered a capital expenditure under this Article if the person had acquired it by purchase*.

N.C.G.S. § 131E-176(2d)(emphasis added).

Hope has submitted with the Request a certified estimate for its proposed expansion that shows a total capital cost of $1,946,052. However, the estimate does not include any costs related to the Equipment, or the fair market value of the Equipment, which clearly are capital expenditures for this contemplated project. Hope's submission, therefore, is insufficient to justify its contention that it and the Provider will have a capital expenditure of less than $2,000,000. Given the nature of the Equipment generally described in the Request, it is highly unlikely to have a fair market value and associated costs of less than $55,000, which is the approximate amount required to exceed $2,000,000.

Hope has not submitted sufficient information to determine the exact capital expenditure. If the assumption as to the cost or fair market value of the Equipment is correct, the transaction is a new institutional health service that requires a CON.

3. **Major Medical Equipment**

"The acquisition by purchase, donation, lease, transfer, or comparable arrangement by any person of major medical equipment" is a new institutional health service. N.C.G.S. § 131E-176(16)p. "Major medical equipment" is defined as:

> a single unit or single system of components with related functions which is used to provide medical and other health services and which costs more than seven hundred fifty thousand dollars ($750,000). In determining whether the major medical equipment costs more than seven hundred fifty thousand dollars ($750,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the major medical equipment shall be included. The capital expenditure for the equipment shall be deemed to be the fair market value of the equipment or the cost of the equipment, whichever is greater. Major medical equipment does not include replacement equipment as defined in this section.

N.C.G.S. § 131E-176(14o).

Hope has provided no information about the cost or fair market value of the Equipment to either itself or the Provider. Therefore, I must decline to rule that the Equipment is outside the definition of major medical equipment subject to the CON requirement.

Miscellaneous Matters.

The Request raises several other issues that I will address briefly.

In addition to the categories of new institutional health service discussed above, Hope argues that the Equipment is not mobile medical equipment within the meaning of N.C.G.S. § 131E-176(16)s. Based on the limited description in the Request about the Equipment, I cannot determine whether the Equipment is mobile or not, and therefore the Request does not support a determination about the applicability of this category to the proposed transaction. The implication from the Request is that the Equipment is fixed rather than mobile.

Hope asserts a wide range of canons of statutory interpretation, most of which apply only when statutory language or legislative intent is unclear or ambiguous. With respect to the transaction proposed by Hope, the statutory language is clear, and the intent of the General Assembly is plain.

Hope contends that certain prior declaratory ruling and "no review" determinations by the Agency support its position. The determinations it cites are inapposite here for a number of reasons, including the fact that they dealt with equipment that was developed either pursuant to the issuance of a CON or pursuant to a settlement agreement, rather than with new equipment to be offered or developed in North Carolina.

Whether the Provider is from outside North Carolina, and whether the Equipment was initially or is to be purchased by the Provider outside of North Carolina is not a factor in this ruling. The North Carolina CON law does not govern transactions outside the State, but when any person offers or develops a new institutional health service within the State, the CON law applies.

The Commentators have provided a number of useful analyses of the Request. All of the Commentators have put forth theories and cited authority suggesting that I should deny the Request. I have considered all of the Comments as well as the arguments of Hope. To the extent the Commentators' theories and authority are not encompassed in the discussion above, it is not because they lack merit, but rather because they constitute additional bases for denial of the Request.

I also note that Hope refers in the Request to its existing CON for the Facility, dated 13 July 2005. Nothing in this ruling is intended to suggest that implementing the proposed transaction in whole or in part would constitute material compliance with that CON.

The Request lacks sufficient information and specificity to issue the ruling that Hope seeks. However, it does describe the proposed transaction in enough detail to demonstrate that it would be a violation of the CON law if consummated in the manner described. Therefore, I must deny the Request.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude the Request must be denied.

This the ____ day of January, 2008.

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Robert J. Fitzgerald, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by certified mail, return receipt requested, by depositing the copy in an official depository of the United States postal service in a first class, postage prepaid envelope addressed as follows:

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This _____ day of January, 2008.

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Jeff Horton
Chief Operating Officer