



North Carolina Department of Health and Human Services
Division of Health Service Regulation
Certificate of Need Section

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

www.ncdhhs.gov/dhsr

Craig R. Smith, Section Chief
Phone: 919-855-3875
Fax: 919-733-8139

January 6, 2012

William R. Shenton
Poyner Spruill
P.O. Box 1801
Raleigh, NC 27602-1801

RE: No Review:

- Transfer by Cancer Centers of North Carolina – Asheville, P.C. (CCNC Asheville) of 100% of its ownership interests in the existing oncology treatment center located at 20 Medical Park Drive, Asheville (Oncology Center) to AHLC, LLC, a wholly-owned subsidiary of CCNC Asheville
- Transfer by AOR Management Company of Virginia, LLC (AOR) of 100% of its ownership interests in the Oncology Center to Asheville CC, LLC, a wholly-owned subsidiary of AOR
- Acquisition of 100% of AHLC, LLC by North Carolina Radiation Therapy Management Services, LLC (NCR TMS)
- Acquisition of 100% of Asheville CC, LLC by NCR TMS
Buncombe County

Dear Mr. Shenton:


The Certificate of Need (CON) Section received your letter of September 26, 2011 and an email dated December 28, 2011 regarding the above referenced proposals. Based on the CON law **in effect on the date of this response to your request**, the proposals described in your correspondence are not governed by, and therefore, do not currently require a certificate of need. However, please note that if the CON law is subsequently amended such that the above referenced proposals would require a certificate of need, this determination does not authorize you to proceed to develop the above referenced proposals when the new law becomes effective.

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the proposals or in the facts provided in your correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a proposal include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in the original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.

Please contact the CON Section if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,


Martha J. Frisone
Assistant Chief


Craig R. Smith, Chief
Certificate of Need Section

cc: Medical Facilities Planning Section, DHSR



Frisone, Martha

From: S. Todd Hemphill [Hemphill@bcs-law.com]
Sent: Wednesday, December 28, 2011 9:57 AM
To: Smith, Craig; Frisone, Martha
Cc: William R. Shenton (wshenton@poynerspruill.com); Ouchley, Jeremy C
Subject: Request for No Review Determination - Asheville Oncology Treatment Center
Attachments: North Carolina Qualification - Asheville CC.pdf; ART-ORG - AHLC.pdf; CERT ORG - Asheville CC.pdf

Dear Craig and Martha,
Following up on Bill Shenton's September 26, 2011 letter regarding the above matter, please find attached Articles of Organization for AHLC, LLC (the entity owned by the physicians), and the Certificate of Organization and Application for Certificate of Authority for Asheville CC, LLC (the entity owned by AOR Management). I believe this is all the information you need to complete your review of the request, but please feel free to contact me if I can be of further assistance.
Todd

S. Todd Hemphill

Attorney

919.881.0338 Ext. 238

hemphill@bcs-law.com



Bode, Call & Stroupe, LLP

3105 Glenwood Ave, Suite 300

Raleigh, NC 27612

P: 919.881.0338 • F: 919.881.9548

www.bcs-law.com

This e-mail and any attachments hereto, is intended only for use by the addressee(s) named herein and may contain legally privileged and/or confidential information. If you are not the intended recipient of this e-mail, you are hereby notified that the dissemination, distribution or copying of this e-mail, and any attachments hereto, is strictly prohibited by law. If you have received this e-mail in error, please notify the foregoing sender immediately via return email or by telephone (919.881.0338), and delete this message and all attachments from your computer system. Thank you.



NORTH CAROLINA

Department of the Secretary of State

To all whom these presents shall come, Greetings:

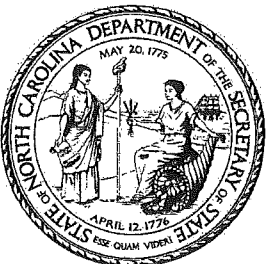
I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

APPLICATION FOR CERTIFICATE OF AUTHORITY

OF

ASHEVILLE CC, LLC

the original of which was filed in this office on the 3rd day of November, 2011.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 3rd day of November, 2011.

Elaine F. Marshall

Secretary of State

State of North Carolina
Department of the Secretary of State

APPLICATION FOR CERTIFICATE OF AUTHORITY
FOR LIMITED LIABILITY COMPANY

Pursuant to §57C-7-04 of the General Statutes of North Carolina, the undersigned limited liability company hereby applies for a Certificate of Authority to transact business in the State of North Carolina, and for that purpose submits the following:

1. The name of the limited liability company is Asheville CC, LLC;
and if the limited liability company name is unavailable for use in the State of North Carolina, the name the limited liability company wishes to use is Asheville CC, LLC **FICTITIOUS NAME NOT FILED IN THIS OFFICE**
2. The state or country under whose laws the limited liability company was formed is: Delaware
3. The date of formation was October 17, 2011; its period of duration is: Perpetual
4. Principal office information: (Select either a or b.)
 - a. The limited liability company has a principal office.
The street address and county of the principal office of the limited liability company is:
Number and Street 10101 Woodloch Forest Drive
City, State, Zip Code The Woodlands, TX 77380 County Montgomery
The mailing address, *if different from the street address*, of the principal office of the corporation is:

 - b. The limited liability company does not have a principal office.
5. The street address and county of the registered office in the State of North Carolina is:
Number and Street 327 Hillsborough Street
City, State, Zip Code Raleigh, NC 27603 County Wake
6. The mailing address, *if different from the street address*, of the registered office in the State of North Carolina is:

7. The name of the registered agent in the State of North Carolina is: Corporation Service Company

CORPORATIONS DIVISION

-P. O. BOX 29622

RALEIGH, NC 27626-0622

(Revised January 2002)

(Form L-09)

APPLICATION FOR CERTIFICATE OF AUTHORITY

Page 2

8. The names, titles, and usual business addresses of the current managers of the limited liability company are: (use attachment if necessary)

<u>Name</u>	<u>Business Address</u>
AOR Management Company of Virginia, LLC	10101 Woodloch Forest Drive, The Woodlands, TX 77380

9. Attached is a certificate of existence (or document of similar import), duly authenticated by the secretary of state or other official having custody of limited liability company records in the state or country of formation. **The Certificate of Existence must be less than six months old. A photocopy of the certification cannot be accepted.**

10. If the limited liability company is required to use a fictitious name in order to transact business in this State, a copy of the resolution of its managers adopting the fictitious name is attached.

11. This application will be effective upon filing, unless a delayed date and/or time is specified: _____

This the 15th day of Nov., 2011

Asheville CC, LLC
AOR Management Company of Virginia, LLC, Member

Name of Limited Liability Company



Signature of Manager

Bruce D. Broussard, President

Type or Print Name

Authorized to sign in accordance with NCGS 57c-3-24"

Notes:

1. Filing fee is \$250. This document must be filed with the Secretary of State.

CORPORATIONS DIVISION
(Revised January 2002)

P. O. BOX 29622

RALEIGH, NC 27626-0622
(Form L-09)

Delaware

PAGE 1

The First State

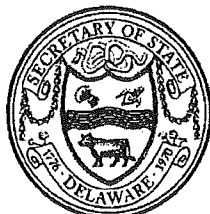
I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ASHEVILLE CC, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIRST DAY OF NOVEMBER, A.D. 2011.

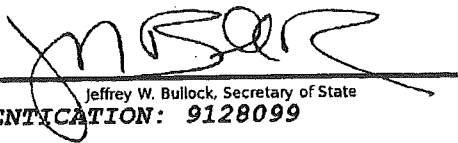
AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE NOT BEEN ASSESSED TO DATE.

5051933 8300

111155025

You may verify this certificate online
at corp.delaware.gov/authver.shtml




Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 9128099

DATE: 11-01-11



NORTH CAROLINA

Department of the Secretary of State

To all whom these presents shall come, Greetings:

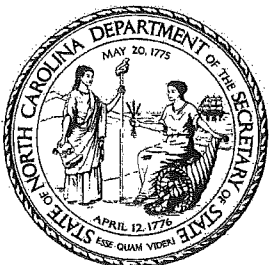
I, Elaine F. Marshall, Secretary of State of the State of North Carolina, do hereby certify the following and hereto attached to be a true copy of

ARTICLES OF ORGANIZATION

OF

AHLC, LLC

the original of which was filed in this office on the 20th day of December, 2011.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 20th day of December, 2011.

Elaine F. Marshall

Secretary of State

State of North Carolina
Department of the Secretary of State

SOSID: 1235047
Date Filed: 12/20/2011 1:48:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C201135400200

Limited Liability Company
ARTICLES OF ORGANIZATION

Pursuant to §57C-2-20 of the General Statutes of North Carolina, the undersigned does hereby submit these Articles of Organization for the purpose of forming a limited liability company.

1. The name of the limited liability company is: AHLC, LLC

2. If the limited liability company is to dissolve by a specific date, the latest date on which the limited liability company is to dissolve: *(If no date for dissolution is specified, there shall be no limit on the duration of the limited liability company.)*

3. The name and address of each person executing these articles of organization is as follows:
(State whether each person is executing these articles of organization in the capacity of a member, organizer or both. Note: This document must be signed by all persons listed here).
Don Jackson, M.D., Organizer, Member
20 Medical Park Dr.
Asheville, NC 28803

4. The street address and county of the initial registered office of the limited liability company is:
Number and Street 20 Medical Park Dr., Asheville, NC 28803
City, State, Zip Code Asheville, NC 28803 County Buncombe

5. The mailing address, *if different from the street address*, of the initial registered office is:

6. The name of the initial registered agent is Don Jackson, M.D.

7. Principal office information: *(Select either a or b.)*
 - a. The limited liability company has a principal office.
The street address and county of the principal office of the limited liability company is:
Number and Street 20 Medical Park Dr.
City, State, Zip Code Asheville, NC 28803 County Buncombe
The mailing address, *if different from the street address*, of the principal office of the corporation is:

 - b. The limited liability company does not have a principal office.

8. Check one of the following:

(i) **Member-managed LLC**: all members by virtue of their status as members shall be managers of this limited liability company.

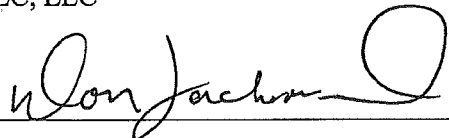
(ii) **Manager-managed LLC**: except as provided by N.C.G.S. Section 57C-3-20(a), the members of this limited liability company shall not be managers by virtue of their status as members.

9. Any other provisions which the limited liability company elects to include are attached.

10. These articles will be effective upon filing, unless a date and/or time is specified:

This is the 15 day of December 2011

AHLC, LLC



Don Jackson, M.D., Member-Manager

NOTES:

1. Filing fee is \$125. This document must be filed with the Secretary of State.

CORPORATIONS DIVISION
(Revised January 2002)

P.O. Box 29622

RALEIGH, NC 27626-0622
(Form L-01)

Instructions for Filing

Delaware

PAGE 1

The First State


I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ASHEVILLE CC, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF OCTOBER, A.D. 2011.

5051933 8300

111105649

You may verify this certificate online
at corp.delaware.gov/authver.shtml




Jeffrey W. Bullock, Secretary of State
AUTHENTICATION: 9097279

DATE: 10-17-11

State of Delaware
Secretary of State
Division of Corporations
Delivered 10:52 AM 10/17/2011
FILED 10:52 AM 10/17/2011
SRV 111105649 - 5051933 FILE

STATE of DELAWARE
LIMITED LIABILITY COMPANY
CERTIFICATE of FORMATION

First: The name of the limited liability company is Asheville CC, LLC

Second: The address of its registered office in the State of Delaware is 2711
Centerville Road, #400 in the City of Wilmington.
Zip code 19808. The name of its Registered agent at such address is
Corporation Service Company

Third: (Use this paragraph only if the company is to have a specific effective date of
dissolution: "The latest date on which the limited liability company is to dissolve is
_____")

Fourth: (Insert any other matters the members determine to include herein.)

Sole Member: AOR Management Company of Virginia, LLC

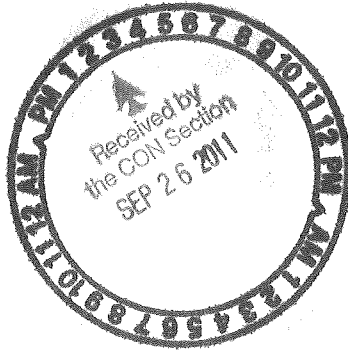
In Witness Whereof, the undersigned have executed this Certificate of Formation this

17th day of October, 2011.

By: [Signature]
Authorized Person (s)

Name: Bruce D. Broussard

WSS



Poyner Spruill^{LLP}

September 26, 2011

William R. Shenton
Partner
D: 919.783.2947
F: 919.783.1075
wshenton@poynerspruill.com

Via Hand Delivery

Mr. Craig R. Smith, Chief
Certificate of Need Section
Division of Health Service Regulation
North Carolina Department of Health and Human Services
809 Ruggles Drive
Raleigh, North Carolina 27603

RE: Request for No Review Determination – Acquisition of Ownership Interests in Corporate Entities that Own Cancer Centers of North Carolina’s Asheville Oncology Treatment Center

Dear Mr. Smith:

We are submitting this letter on behalf of our client, Radiation Therapy Services, Inc. (“RTS”), as well as its wholly-owned subsidiary, North Carolina Radiation Therapy Management Services, LLC (“NCRTMS”). RTS is a national provider of radiation oncology services which offers services at several locations in western North Carolina.

With this letter, NCRTMS is requesting a no-review determination regarding its acquisition of the ownership interests in the corporate entities that own an existing oncology treatment center and the associated equipment located in Asheville, North Carolina. Consistent with the longstanding approach of the Agency in finding that purchases of corporate ownership interests are not events requiring a certificate of need, NCRTMS now seeks confirmation that its acquisition of membership interests in the corporate entities owning the existing Asheville oncology treatment center, including a linear accelerator and computed tomography scanner, and its continued operation of that oncology treatment center and the same equipment, at the same site, may proceed without first obtaining a certificate of need.

FACTUAL BACKGROUND

The Parties

Since 2004, Cancer Centers of North Carolina – Asheville, P.C. (“CCNC-Asheville”) and AOR Management Company of Virginia, LLC (f/k/a AOR Management Company of Virginia, Inc.) (“AOR”), an indirect, wholly-owned subsidiary of US Oncology, Inc. (“USON”), together have owned and operated an oncology treatment center that is located at 20 Medical Park Drive, Asheville, North Carolina (the “Oncology Center”).¹ This Oncology Center uses a Varian 2100C linear accelerator (the “Linac”) and a computed tomography scanner (the “CT Scanner”) to provide radiation therapy services to patients. As discussed further below, the Linac and CT Scanner were acquired, and have been used to provide radiation therapy services, under an exemption from certificate of need (“CON”) review that was recognized by the Certificate of Need Section (“CON Section”). After an appeal of this determination, the CON Section’s decision to grant an exemption was upheld.

¹ CCNC-Asheville was formerly known as Asheville Hematology and Oncology Associates, P.A. (“AHO”). The corporate name was changed in 2009. See Exhibit 1. AOR was formerly a corporation, but has converted to a limited liability company. See Exhibit 2.

CCNC-Asheville is a professional corporation organized under the laws of the State of North Carolina with its principal place of business located at 20 Medical Park Drive, Asheville, North Carolina. It employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of the Linac and CT Scanner located at the Asheville Oncology Center on Medical Park Drive. CCNC-Asheville has served cancer patients in the Asheville area since 1982 when the practice (then AHO) was first formed and began providing medical oncology services. Its oncology treatment center is a "grandfathered" facility because it became operational before the CON Law was amended to apply to oncology treatment centers. See 2004 correspondence between AHO and CON Section (without exhibits) (Exhibit 3).

USON is a business corporation organized under the laws of the State of Delaware, with its principal place of business located at 10101 Woodloch Forest Drive, The Woodlands, Texas 77380. Through its subsidiaries, USON provides administrative support for oncology practices throughout the United States, and also furnishes medical equipment used by those practices. One of those subsidiaries is AOR, a Delaware limited liability company.

RTS (also known as 21st Century Oncology) operates several radiation therapy centers in western North Carolina, including one located in a medical office building in Asheville which was the site of a damaging fire that occurred on July 28, 2011, and which was reported to you in an earlier letter. Federal and State investigators have indicated they believe this fire may have been intentionally set; but because the investigation of the fire is still in process, RTS has not been able to access this center and assess the damage and determine when and how it might be re-opened. Once a damage assessment is completed, RTS will approach the CON Section about the status of the center, including any steps needed to repair or replace it. However, without a full assessment of the status of this site, RTS is uncertain at this point about the steps necessary to resume operations at that center.

Immediately following the fire, RTS successfully transitioned cancer patients who had been receiving treatment at its Asheville center to its other treatment centers in western North Carolina, where they are continuing to receive consultations and radiation therapy treatment. The transaction proposed in this letter would facilitate the resumption of RTS's provision of radiation therapy services to patients closer to Asheville, and accordingly RTS and NCRTMS request that the Agency expedite its consideration of this no-review request.

NCRTMS is a North Carolina limited liability company which is a wholly-owned subsidiary of RTS. NCRTMS provides management and administrative support services for RTS's radiation therapy centers in North Carolina.

RTS, NCRTMS, CCNC-Asheville and AOR (collectively, the "Parties") have discussed and reached agreement on a transaction that would involve the transfer of the membership interests in the corporate entities that own the Oncology Center and the equipment used to provide treatment for patients at the Oncology Center, including the Linac and CT Scanner (collectively, the "Equipment"). The transaction would be limited to a transfer of the underlying ownership interests in the corporate entities that own the Oncology Center and the Equipment (the "Proposed Transaction"). The Oncology Center and its Equipment will continue to serve patients at the same location, and there will be no change in the scope of services provided by the Oncology Center as part of the Proposed Transaction. The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change as a result of the transaction. Based upon prior

declaratory rulings and "no review" determinations that have been issued by the Office of the Director of the Division of Health Services Regulation and by the CON Section, it is clear that the Proposed Transaction agreed upon by the Parties is not a "New Institutional Health Service," and should be permitted to proceed without first obtaining a certificate of need.

This letter describes the Proposed Transaction and identifies the grounds for a determination that the transaction is not subject to CON review.

Background on the Oncology Center and Equipment

In 2005, AHO (now CCNC-Asheville) relocated its Asheville offices to establish the current Oncology Center. AHO acquired the Linac and CT Scanner to provide radiation therapy services to patients. The Linac that has been operated at the Oncology Center is recognized in the Linac Inventory in the State Medical Facilities Plan. See Draft 2012 State Medical Facilities Plan, p. 147 (Exhibit 4). As you will recall, the present Oncology Center was developed under an exemption from CON review recognized by the CON Section. In February 2005, AHO sought "no review" determinations for a proposed relocation and expansion of its oncology treatment center and acquisition of medical equipment that would allow AHO to provide radiation therapy. See AHO No-Review Requests and Related Correspondence (without exhibits) (Exhibit 5). AHO presented four proposals: (1) acquisition of a linear accelerator, (2) acquisition of a CT scanner, (3) acquisition of treatment planning equipment, and (4) relocation of its oncology treatment center. On August 2, 2005, the CON Section issued four "no review" letters, confirming that none of the proposals required a certificate of need. See CON Section No-Review Determinations (Exhibit 6).

The CON Section's determinations were challenged and following a lengthy contested case and appeal, the North Carolina Court of Appeals ultimately affirmed the Final Agency Decision, entered by the Acting Director of the Division of Faculty Services (the "Division") that AHO's acquisition of the Linac and CT scanner and expansion of the oncology treatment center did not require a CON. See *Mission Hospitals, Inc. v. N.C. DHHS*, 696 S.E.2d 163 (N.C. Ct. App. 2010) (Exhibit 7).

At the heart of the appeal challenging the CON Section's no-review determinations were amendments to the CON Law which took effect in late August 2005. Before late August 2005, oncology treatment centers were among the services regulated by the CON Law, and a certificate of need was required to develop an oncology treatment center. But on August 26, 2005, the CON Law was amended by deleting the term "oncology treatment center" from the group of facilities defined as a "health service facility" under N.C. Gen. Stat. § 131E-176. Along with this change, the list of new institutional health services for which a certificate of need is required was amended to add any acquisition of a linear accelerator occurring on or after the effective date of the amendment. AHO's no-review requests and the CON Section's subsequent no-review determinations preceded the August 26, 2005 amendment that eliminated the concept of oncology treatment centers and established a requirement for a certificate of need to acquire a linear accelerator.

In its decision, the Court of Appeals recognized that AOR provided substantial administrative support for AHO's day-to-day operations under a Management Services Agreement which also authorized AOR to acquire equipment for AHO. The Court of Appeals concluded that: (1) AHO's February 2005 requests seeking CON determinations regarding its proposals were made in good faith reliance on the CON Law then in existence; (2) AHO had acquired vested rights to develop its proposed services under the prior version of the CON Law because of the building lease entered into by AHO's managing agent, and AHO's acquisition by comparable arrangement of the Linac through a purchase contract entered into by AOR; and (3) the CON Section had issued its no-review determinations prior to

the effective date of the amendment to the CON Law. Accordingly, the Court of Appeals held that the CON Section and the Division in its Final Agency Decision properly applied the CON Law as it existed when AHO submitted its no-review requests. The Court of Appeals also affirmed the Final Agency Decision's determinations that AHO's acquisition of the CT Scanner did not require a CON because the total costs to buy the CT Scanner and make it operational were below the threshold dollar amount for a diagnostic center, and that the relocation and expansion of AHO's oncology treatment center did not require a CON because the costs related to such relocation and expansion did not exceed \$2,000,000. Thus, the Court of Appeals conclusively determined that the relocation and expansion of AHO's (now CCNC-Asheville's) oncology treatment center and AHO's acquisition of the Linac and CT Scanner did not require a certificate of need.

The Proposed Transaction

The Proposed Transaction to transfer the ownership interests in the corporate entities that own the Oncology Center and Equipment will proceed in two steps. First, CCNC-Asheville will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary ("CCNC Sub"), and AOR will transfer its interest in the Oncology Center and Equipment to a wholly-owned subsidiary (collectively with CCNC Sub, the "LLCs"). The transaction will be completed with NCR TMS purchasing all of the membership interests in those two LLCs as a second step.

After the Proposed Transaction is complete, the LLCs will continue to exist as legal business entities, and will continue to own the Oncology Center and Equipment, including the Linac and CT Scanner that the CON Section (and the Court of Appeals) determined were not subject to CON review. The Oncology Center and its Equipment will continue to serve patients at the same location at 20 Medical Park Drive in Asheville. There will be no purchase of additional equipment, nor will any new services be offered, as a result of the Proposed Transaction. The only change will be the membership composition of the corporate entities that own the Oncology Center and Equipment, with CCNC-Asheville and AOR initially transferring their ownership interests to the wholly-owned subsidiary LLCs, followed by a separate transaction in which NCR TMS will acquire all of the membership interests in the LLCs.

The LLCs will not offer any medical services. All medical services associated with oncology treatment at the center will be furnished by licensed physicians. The Parties anticipate that the radiation oncologists who have been practicing with CCNC-Asheville and have supervised the care of a significant majority of the patients receiving treatment at the Oncology Center in the past will continue to supervise and direct the treatment of patients under their care. Under an agreement that preserves the physicians' authority over all clinical and medical decisions, the LLCs will make the Linac and CT Scanner available for treatment of patients by the CCNC-Asheville radiation oncologists and other licensed physicians authorized to care for patients at the Oncology Center.

Based upon the long-standing approach that the Division and the CON Section have taken to the purchase of equity interests in existing North Carolina health care facilities when there is no change in the services offered or the equipment employed to offer the services, NCR TMS respectfully submits that none of these steps relating to the Proposed Transaction constitutes a New Institutional Health Service that requires a certificate of need.

ANALYSIS

The CON Law was enacted to prevent the development and operation of unneeded health services, equipment and facilities. This is made explicit in the very first section of the law, where the General Assembly finds: "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." N.C. Gen. Stat. § 131E-175(4). The CON Law essentially focuses on the development and offering of those "new institutional health services" that would create additional capacity, and which are catalogued in N.C. Gen. Stat. § 131E-176(16). Each of these new institutional health services entails in some way the acquisition or establishment of a *new* health service, *new* equipment, *new* facilities, or expansions and relocations of existing facilities or services (which also would have an impact on how health services are deployed and utilized). In keeping with its fundamental goals, the CON Law expressly recognizes that certain activities are not subject to review. Based upon the clear terms of the CON Law and prior declaratory rulings by the Department, the Proposed Transaction does not require a certificate of need.

The Proposed Transaction Will Not Result in a New Institutional Health Service

The CON Law provides that no person shall offer or develop a "new institutional health service" without first obtaining a CON. N.C. Gen. Stat. § 131E-178. However, none of the components of the "new institutional health service" definition address, directly or indirectly, the acquisition of membership interests in an organization that already is operating a health service. This type of transaction is among the activities that are "administrative and other activities that are not integral to clinical management," and which are specifically excluded from the definition of "health service" in the CON Law. N.C. Gen. Stat. § 131E-176(9a). Therefore, an acquisition of corporate ownership interests, such as the Proposed Transaction at issue in this request, does not involve a new institutional health service at all and should not be subject to CON Review.

The list of new institutional health services does include "the acquisition by purchase, donation, lease, transfer or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and "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," N.C. Gen. Stat. § 131E-176(16)(b). However, neither of these definitions applies to the Proposed Transaction. In prior declaratory rulings and no review determinations, the Department and CON Section have consistently recognized that transactions which are limited to an acquisition of underlying corporate membership interests in an existing legal entity which owns and operates an existing oncology center and its associated equipment, such as the Proposed Transaction, fall within the above-referenced exclusion recognized in the definition of "health service" in the CON Law. Accordingly, the Department and CON Section have consistently determined that events such as the Proposed Transaction do not trigger certificate of need review under either the linear accelerator acquisition or the \$2,000,000 capital expenditure provision.

The Department's Prior Declaratory Rulings Confirm the Transaction Does Not Require a CON

This No-Review Request is consistent with the Department's prior declaratory rulings which have interpreted the applicability of the CON Law to the purchase of ownership interests in corporate entities that own existing health care facilities. Over the course of North Carolina's Certificate of Need program, there have been a number of declaratory rulings which confirmed that the acquisition of ownership interests in companies which own existing health care facilities that already are offering services does not constitute the offering of a new institutional health service because such transactions do not implicate the creation of additional capacity and health service facilities which might lead to the "unnecessary use and expense of resources and overutilization of healthcare services," detailed in the legislative findings. See N.C. Gen. Stat. § 131E-175(4). Several examples of declaratory rulings which have upheld this principle of no review for acquisitions of corporate ownership interests are discussed below.

In at least four rulings that were issued after the enactment of the August 2005 amendment to the CON Law, the Department has determined specifically that the transfer of ownership interests in organizations that own linear accelerators does not require a certificate of need.

- On August 18, 2011, the Department issued a declaratory ruling finding that Radiation Oncology Centers of the Carolinas, Inc.'s transfer of two CON-approved radiation oncology facilities to two wholly-owned subsidiaries did not constitute a new institutional health service or require a certificate of need. *See In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.* (Exhibit 8).
- On September 27, 2010, the Department issued a declaratory ruling confirming that the acquisition by Cancer Centers of North Carolina, P.C. of the majority of the membership interests in Wake Radiology Oncology Services and the continued operation of WROS's oncology treatment center did not require a certificate of need. *See In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc. et al.* (Exhibit 9).
- On December 21, 2007, the Department issued a declaratory ruling finding that Rex Healthcare, Inc.'s acquisition of 100% of the membership interest of Smithfield Radiation Oncology, LLC, which owned and operated a linear accelerator, was not subject to CON review. *See In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC* (Exhibit 10).
- On September 14, 2007, the Department issued a declaratory ruling confirming that certificate of need review was not required for the sale to another entity of 100% of the issued and outstanding stock of a company that owned a linear accelerator. *See In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.* (Exhibit 11).

At issue in the August 2011 declaratory ruling involving Radiation Oncology Centers of the Carolinas, Inc. ("ROCC"), was the proposed transfer of two existing oncology facilities owned by ROCC to two wholly-owned subsidiaries of ROCC. The two oncology facilities each operated a linear accelerator and CT simulator, the acquisition of which had previously been approved by the CON Section. The Department concluded that this transaction was not subject to CON review. As the Declaratory Ruling explained, "The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. . . . The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change." The transaction at issue in the ROCC declaratory ruling is very similar to the first step of the Proposed Transaction at issue in this request, under which CCNC-Asheville and AOR will transfer their interests in the existing Oncology Center and its associated Equipment to two wholly-owned subsidiary LLCs.

In the September 2010 declaratory ruling involving Wake Radiology Oncology Services, the Department reviewed a proposed transaction under which WROS would be converted from a professional limited liability company to a limited liability company, followed immediately by the sale of the ownership interests in WROS to Cancer Centers of North Carolina, P.C. Subsequently, in a separate transaction, WakeMed proposed purchasing a minority membership interest in the renamed WROS entity. After the two transactions, the resulting LLC would continue to exist as a legal and business entity and would continue to own the oncology center and equipment that was authorized by a previously issued CON. The Department concluded that these proposed transactions did not require a certificate of need. In its

Declaratory Ruling, the Department noted that the entity which owned the Linac and Simulator would not change and the same equipment would continue to be used to provide the same radiation oncology services at the same location. The Declaratory Ruling explained that although the proposed transaction involved expenditures by CCNC and WakeMed, "these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed." The transactions involved in the WROS declaratory ruling are analogous to the second step of the Proposed Transaction at issue in this request, under which NCRTMS will acquire ownership interests in two existing LLCs which own the Oncology Center and its associated Equipment which will continue to provide the same services to patients at the same location following the transaction.

In its September 2007 declaratory ruling involving NCRTMS, the Department reviewed a request that involved the purchase of all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC"). In its declaratory ruling request, CRTC stated that it was operating one linear accelerator and simulator that were in the Department's equipment inventory reports, as well as an additional linear accelerator that was not listed in the inventory. After reviewing the proposed transaction, the Department concluded, as to the one linear accelerator and simulator that were in the equipment inventory reports, that the proposed stock purchase could proceed without a CON. The Declaratory Ruling stated: "The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change." The Department's ruling permitted all of the stock of CRTC, which owned the linear accelerator and simulator, to be purchased without a certificate of need.

The purchase of LLC interests proposed by the Parties in this Request is analogous to the stock purchase that was proposed by CRTC. The Proposed Transaction will entail acquisition by NCRTMS of all of the ownership interests in the LLCs. Ownership of the Oncology Center and its associated Equipment, including the Linac and CT Scanner, will remain with the LLCs following the second step of the Proposed Transaction.

In the December 2007 declaratory ruling involving Smithfield Radiation Oncology, the Department reached a similar conclusion. In that situation, Rex Healthcare already had a 25% ownership interest in Smithfield Radiation Oncology, LLC ("SRO"), and proposed to acquire the remaining 75% of the ownership interests from the physician owners. The Department concluded that "[t]he transaction described by Petitioners does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change." Thus, the Department concluded that these purchases of the ownership interests of companies which own an operating linear accelerator did not require a CON.

The Department also issued a similar ruling with regard to acquisition of the stock of a company that owned heart lung bypass equipment. See *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*, January 24, 2008 (Exhibit 12). Heart-lung bypass machines are another type of medical equipment for which a certificate of need is required under N.C. Gen. Stat. § 131E-176 (16) (f1), the same portion of the definition of new institutional health services that applies to purchases of linear accelerators. The Department focused on the fundamental fact that the ownership of the equipment would not change, and that there was no purchase of equipment, in ruling that this stock acquisition did not require a Certificate of Need. The Department's determination in these rulings is firmly founded on the express terms of the CON Law.

The Proposed Transaction Is Not an Acquisition of a Linear Accelerator

The proposed acquisition of 100% of the membership interests in the LLCs by NCRTMS does not constitute the acquisition of a linear accelerator. As explained above, the transaction is limited to the acquisition of the underlying ownership interests in the corporate entities that own the existing Oncology Center and its associated Equipment. The Linac will continue to be used to provide the same radiation oncology services, in the same location, and the entity that owns the Linac will not change as a result of Step 2 of the Proposed Transaction. The LLCs will continue to own the Linac and the CT Scanner as well as all the Oncology Center assets that were found to be exempt from CON review and have been used to furnish oncology treatments to patients. The LLCs' membership composition will change to a single member, NCRTMS, but their legal status as existing business entities will not change.

Since the LLCs will remain the same legal entities, the same "person" will own the equipment and operate the Oncology Center and its Equipment following the Proposed Transaction's second step. See N.C. Gen. Stat. § 131E-176(19) and 178. There will be no change in the operation of the Oncology Center. Accordingly, and consistent with the rulings issued since the August, 2005 amendment, there is no basis to require CON review of the Proposed Transaction as an acquisition of a linear accelerator under the provisions of N.C. Gen. Stat. § 131E-176(16)(f1)5a.

The Proposed Transaction Does Not Involve the Development or Expansion of a Health Service Facility

The Proposed Transaction will involve expenditures by NCRTMS, but these will simply be purchases of ownership interests in existing LLCs that own the Oncology Center. They will not entail a capital expenditure to develop or expand a health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed.

Likewise, the Proposed Transaction will not entail "a capital expenditure . . . which relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The only change that will result from the Proposed Transaction will be in the membership composition of the LLCs, and that change in ownership is not a health service.

As the Department must have determined in the prior declaratory rulings discussed above, the purchase of ownership interests in an existing enterprise, which already is lawfully operating the equipment and offering the services, is not a capital expenditure that "relates to the provision of a health service" under N.C. Gen. Stat. § 131E-176(16)(b). The definition of "health service" in the CON Law specifically excludes "administrative and other activities that are not integral to clinical management." N.C. Gen. Stat. § 131E-176(9a). The membership composition of the LLCs is not integral to the clinical management of the Oncology Center, and the Center's operations will not change as a result of the Proposed Transaction. Therefore, the purchase of membership interests in the LLCs is not an activity that is "integral to clinical management," and accordingly is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C. Gen. Stat. § 131E-176(16)(b).

Issuance of the No-Review Determination Is Consistent with the Purposes of the CON Law

The CON Law is intended to regulate new institutional health services and is not intended to impede routine business transactions such as an acquisition of a limited liability company's ownership interests. The only point when the CON Law does limit changes in ownership is "before completion of the project or operation of the facility . . ." N.C. Gen. Stat. § 131E-189(c). CCNC-Asheville and AOR have operated the Oncology Center for more than a year², so this restriction in the CON Law clearly does not apply.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the State's inventory of linear accelerators will not change. The Oncology Center and its Equipment have been established and operating for years. No new, or additional equipment will be acquired or placed in operation in the State. No new facility will be established nor new services offered. As a result, the Proposed Transaction does not implicate the fundamental objective of the CON Law -- to control the development and expansion of health service facilities. Although not applicable to the Parties' Proposed Transaction, in keeping with this overarching objective, the CON Law actually contains a provision, in N.C. Gen. Stat. § 131E-184(a)(8), which recognizes that an outright purchase of all the assets of an entire health service facility is exempt from the requirement of obtaining a CON, even if the purchased facility contains equipment that would otherwise be subject to CON review.

The purposes for which the CON Law was enacted are not served by regulating the purchase and sale of the underlying membership interests in corporate entities that own existing health service facilities or equipment which the CON Section has already determined to be needed. If membership interests in companies that own an existing health service facility are purchased, without any accompanying addition, expansion, reduction, or relocation of the services offered, then none of the underlying policy concerns that are the basis for the CON Law come into play.

CONCLUSION

For all of the foregoing reasons, the regulation of events like the Proposed Transaction, involving existing and previously reviewed and approved facilities and their associated equipment which do not otherwise implicate the fundamental purposes of the CON Law stated in N.C. Gen. Stat. § 131E-175, is beyond the scope of the CON Law, and should not require a CON. As stated above, since the expansion of the Oncology Center pursuant to the exemption recognized by the CON Section, the Linac, CT Scanner, and related equipment have been operated as part of an ongoing health care facility and that will continue after completion of the Proposed Transaction.

The North Carolina courts have recognized that because the CON Law interferes with the normal right to do business, it must be narrowly construed. See *HCA Crossroads Residential Centers, Inc. v. N.C. Dep't of Human Resources*, 327 N.C. 573, 579, 398 S.E.2d 466, 470 (1990) ("When viewed in its entirety, Article 9 of Chapter 131E of the General Statutes, the Certificate of Need Law, reveals the

² As you may be aware, AHO (now CCNC-Asheville) operated the Oncology Center in 2006, but the operation of the Equipment was stayed after the initial Final Agency Decision on AHO's no review request reversed the CON Section's initial determination and the Recommend Decision. CCNC-Asheville was not able to fully reinstate operation of the Equipment until after the Court of Appeals' decision in 2010 affirming the second Final Agency Decision which upheld the CON Section's initial determination.

Mr. Craig R. Smith
Chief, CON Section
September 26, 2011
Page 10

Poyner Spruill^{LLP}

legislature's intent that an applicant's fundamental right to engage in its otherwise lawful business be regulated but not be encumbered with unnecessary bureaucratic delay.") Failure to issue the requested no-review determination would delay and impede the Parties that are requesting this determination in proceeding with a lawful business transaction.

We have enclosed a copy of the materials referenced in this letter (see attached Index). We request your earliest possible attention to this request and look forward to your confirmation that the Proposed Transaction is not a new institutional health service and may proceed without a certificate of need. Thank-you for your attention to this and if there is any additional information you may require, it will be expedited upon receipt of your request.

Sincerely,



William R. Shenton
Partner

Enclosures

cc: Martha Frisone, Assistant Chief, CON Section
Norton L. Travis, General Counsel for RTS
S. Todd Hemphill, Counsel for CCNC-Asheville and AOR
Jeremy C. Ouchley, Counsel for AOR

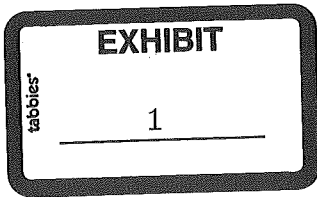
Index to Exhibits

1. Documentation of the CCNC-Asheville corporate name change;
2. Documentation of the conversion of AOR to a limited liability company;
3. 2004 Correspondence between AHO and the CON Section regarding the grandfathered status of AHO's oncology treatment center (without exhibits);
4. Draft 2012 State Medical Facilities Plan excerpt;
5. AHO No-Review Requests regarding the relocation and expansion of its oncology treatment center and acquisition of medical equipment to be used to provide radiation therapy (without exhibits);
6. CON Section No-Review Determinations regarding AHO's relocation and expansion of its oncology treatment center and acquisition of medical equipment;
7. *Mission Hospitals, Inc. v. N.C. DHHS*, 696 S.E.2d 163 (N.C. Ct. App. 2010);
8. August 18, 2011 Declaratory Ruling, *In re: Request for Declaratory Ruling by Radiation Oncology Centers of the Carolinas, Inc.*;
9. September 27, 2010 Declaratory Ruling, *In re: Request for Declaratory Ruling by Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc. et al.*;
10. December 21, 2007 Declaratory Ruling, *In re: Request for Declaratory Ruling by Rex Healthcare, Inc. and Smithfield Radiation Oncology, LLC*;
11. September 14, 2007 Declaratory Ruling, *In re: Request for Declaratory Ruling by Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.*; and
12. January 24, 2008 Declaratory Ruling, *In re: Request for Declaratory Ruling by New Hanover Perfusionists, Inc.*

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Date Filed: 12/7/2009 9:03:00 AM
Elaine F. Marshall
North Carolina Secretary of State
C200933800208

ARTICLES OF AMENDMENT

OF

ASHEVILLE HEMATOLOGY & ONCOLOGY ASSOCIATES, P.A.

The undersigned professional corporation, for the purpose of amending its Articles of Incorporation, and pursuant to the provisions of Section 55B-5 and Section 55-10-06 of the General Statutes of North Carolina, hereby submits these Articles of Amendment.

1. The name of the professional corporation is: Asheville Hematology & Oncology Associates, P.A.

2. The following amendment to the Articles of Incorporation of the professional corporation was adopted by unanimous written consent of its sole shareholder on the 10th day of November, 2009, in the manner prescribed by Chapter 55, North Carolina Business Corporation Act, of the General Statutes of North Carolina:

RESOLVED, that Section 1.1 of Article 1 of the Articles of Incorporation be deleted in its entirety and that a new Section 1.1 of Article 1 be substituted therefor as follows:

1.1 Name and Address. The name and address of the professional corporation is Cancer Centers of North Carolina-Asheville, P.C. (the "Corporation"), 20 Medical Park Drive, Asheville, Buncombe County, North Carolina 28803.

3. These articles will be effective upon filing. This 10th day of November, 2009.

Asheville Hematology & Oncology Associates, P.A.

By: [Signature]

Don V. Jackson, Jr., M.D., President



**NORTH CAROLINA
MEDICAL BOARD**

George L. Saunders, III, MD
President

Donald E. Jablonski, DO
President-Elect

Janice E. Huff, MD
Secretary/Treasurer

Pamela L. Blizzard
Paul S. Camnitz, MD
William W. Foster, MD
Thomas R. Hill, MD
Thelma C. Lennon
John B. Lewis, Jr., LLB
Peggy Robinson, PA-C
Janelle A. Rhyne, MD
William A. Walker, MD

12/02/2009

S. Todd Hemphill
Bode, Call & Stroupe, L.L.P.
3105 Glenwood Avenue, Ste 300
Raleigh, NC 27612

Re: Asheville Hematology & Oncology Associates, P.A.

Dear Mr. Hemphill:

The Board has no objection to Asheville Hematology & Oncology Associates, P.A. changing its name to Cancer Centers of North Carolina-Asheville, P.C. When you have filed the name change with the Secretary of State, please send us a filed copy.

If you have any other questions, please do not hesitate to contact us.

Sincerely,

Barbara Gartside
Corporations Coordinator

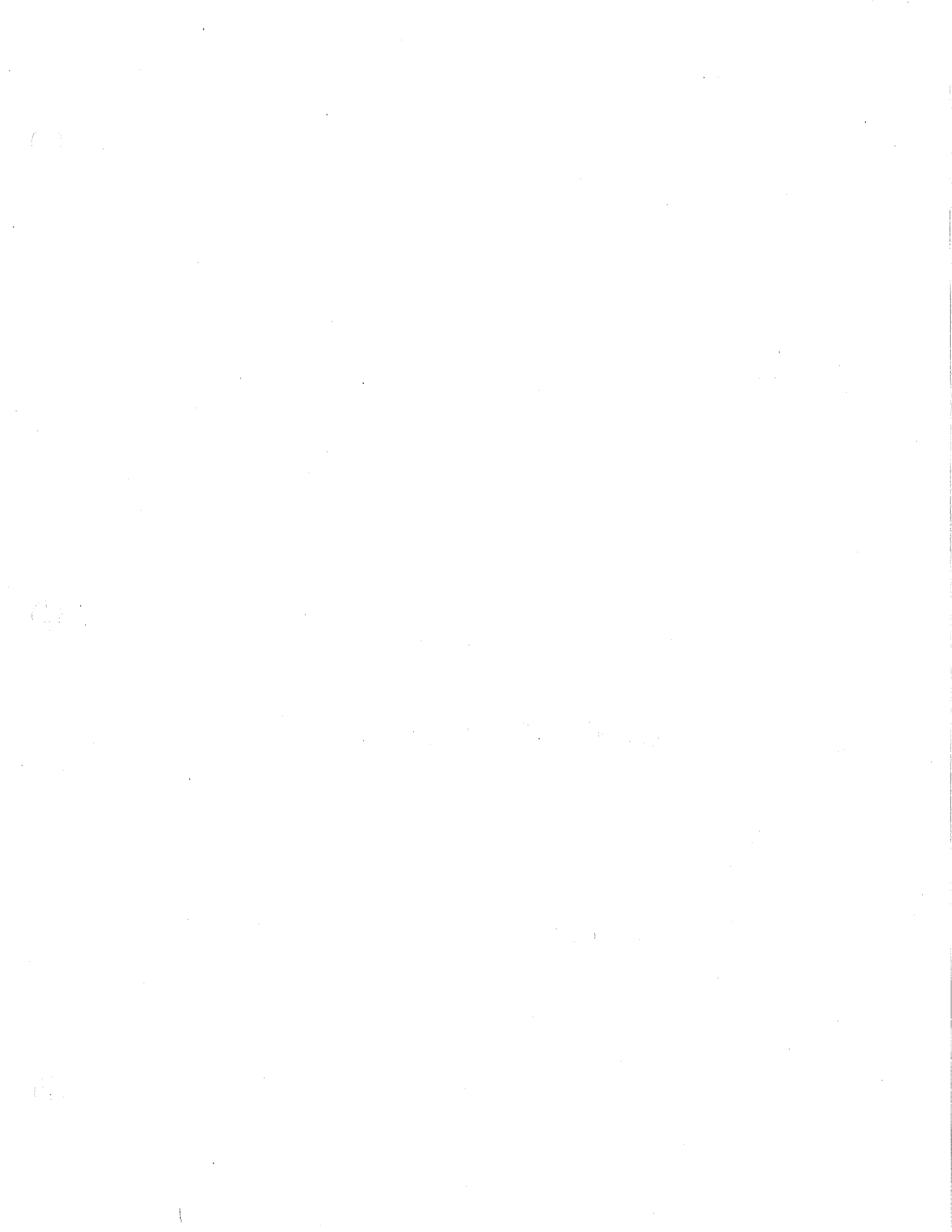
R. David Henderson
Executive Director

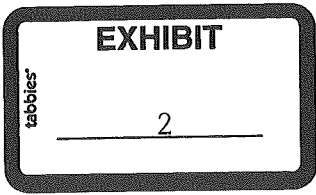
1203 Front Street
Raleigh, North Carolina 27609-7533

Mailing:
P.O. Box 20007
Raleigh, North Carolina 27619-0007

Telephone: (919) 326-1100
Fax: (919) 326-1131
Email: info@ncmedboard.org
Web: www.ncmedboard.org







SOSID: 0659381
Date Filed: 8/8/2008 12:30:00 PM
Elaine F. Marshall
North Carolina Secretary of State
C200822100247

State of North Carolina
Department of the Secretary of State

APPLICATION FOR CERTIFICATE OF WITHDRAWAL
BY REASON OF MERGER, CONSOLIDATION
OR CONVERSION

Pursuant to §55-15-21, §55A-15-21, § 57C-7-12, § 59-91 or § 59-909, of the General Statutes of North Carolina as applicable, the undersigned entity, as the surviving or resulting entity in a statutory merger, consolidation or conversion hereby applies to the Secretary of State for a Certificate of Withdrawal for the foreign entity(ies) authorized to transact business or conduct affairs in the State of North Carolina named below, whose separate existence has ceased as a result of the merger, consolidation or conversion, and for that purpose submits the following statement:

1. The name of the surviving or resulting entity is: AOR Management Company of Virginia, LLC
 - a. The surviving or resulting entity is incorporated, formed or created under the laws of: Delaware
 - b. The type of entity of the surviving or resulting entity: Limited Liability Company
2. The surviving or resulting entity is not authorized to transact business or conduct affairs in the State of North Carolina.
3. The name of each foreign entity authorized to transact business in North Carolina (and its fictitious name used in the State of North Carolina, if different from its official name) is: AOR Management Company of Virginia, Inc.
 - a. The name of the state or country under whose law each such entity was incorporated, formed or created is: Delaware
 - b. The type of entity of each foreign entity: Corporation
4. The surviving or resulting entity hereby consents that service of process based on any cause of action arising in the State of North Carolina, or arising out of business transacted or affairs conducted in this State during the time each foreign entity was authorized to transact business or conduct affairs in this State may thereafter be made by service thereof on the Secretary of State.
5. The mailing address to which the Secretary of State may mail a copy of any process served pursuant to the paragraph above is:

C/O CT Corporation System

Address 225 Hillsborough Street

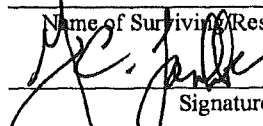
City, State, Zip Code Raleigh, NC 27603
6. The surviving or resulting entity hereby agrees to file a statement of any subsequent change in its mailing address with the Secretary of State.
7. Attached hereto is a copy of the articles of merger, consolidation or conversion or a certificate reciting the facts of the merger, consolidation or conversion duly authenticated by the Secretary of State or other official having custody of records of such entities in the state or country under the laws of which such merger was effected.

8. This application will be effective upon filing, unless a date and/or time is specified here: _____

This the 8th day of August, 2008

AOR Management Company of Virginia, LLC

Name of Surviving/Resulting Entity



Signature

Glen Laschober, manager

Type or Print Name and Title

NOTES

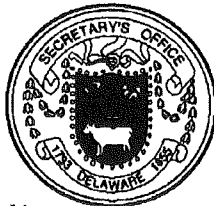
1. Filing fee is \$10. This application must be filed with the Secretary of State. The application must be accompanied by a copy of the articles of merger, consolidation or conversion or a certificate reciting the facts of the merger, consolidation or conversion duly authenticated by the Secretary of State or other official having custody of the records of such entities in the state or country under the laws of which the foreign entity was organized, incorporated or created.
2. This form is to be used only if the surviving corporation is not authorized to transact business or conduct affairs in North Carolina.

Delaware

PAGE 1

The First State

I, HARRIET SMITH WINDSOR, SECRETARY OF STATE OF THE STATE OF DELAWARE DO HEREBY CERTIFY THAT THE CERTIFICATE OF CONVERSION OF A DELAWARE CORPORATION "AOR MANAGEMENT COMPANY OF VIRGINIA, INC." TO A DELAWARE LIMITED LIABILITY COMPANY OF "AOR MANAGEMENT COMPANY OF VIRGINIA, LLC", WAS FILED IN THIS OFFICE ON THE THIRTY-FIRST DAY OF DECEMBER, A.D. 2007, AT 11:36 O'CLOCK A.M.



2532346 8317

080856614

You may verify this certificate online
at corp.delaware.gov/authver.shtml

Harriet Smith Windsor

Harriet Smith Windsor, Secretary of State

AUTHENTICATION: 6780350

DATE: 08-07-08

BODE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW
3105 GLENWOOD AVENUE, SUITE 300
RALEIGH, NORTH CAROLINA 27612

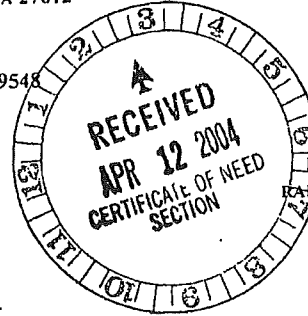
(919) 881-0338
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JOHN T. BODE
W. DAVIDSON CALL
ROBERT V. BODE
ODES L. STROUPE, JR.
V. LANE WHARTON, JR.
S. TODD HEMPHILL
DIANA EVANS RICKETTS
CHRISTIE M. FOPPIANO

JOHN V. HUNTER III
OF COUNSEL

DAVID P. GREEN
(1945 - 1985)

MAILING ADDRESS
POST OFFICE BOX 6338
RALEIGH, NORTH CAROLINA
27628-6338



April 12, 2004

Via Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Paschal, Jackson, Puckett and Davis General Partnership and Asheville Hematology and Oncology Associates, P.A. / Request for determination of Oncology Treatment Center Status, Buncombe County

Dear Ms. Hoffman:

We are writing you on behalf of our clients, Paschal, Jackson, Puckett and Davis General Partnership (hereinafter, the "Partnership") and Asheville Hematology and Oncology Associates, P.A. (hereinafter, the "Practice"), requesting the CON Section to confirm that own and operate, and owned and operated prior to March 18, 1993 an oncology treatment center within the meaning of the CON law.

Facts

The Practice is a North Carolina professional corporation, which was formed in 1982, to engage in the practice of medical oncology. A copy of the Articles of Incorporation for the Practice is attached as Exhibit 1.

The Partnership is a North Carolina General Partnership which was formed in 1984 by the physician owners of the Practice, to purchase real estate in Asheville, Buncombe County, construct a building for a medical oncology practice (hereinafter the "Facility"), and lease the Facility to the Practice. The name of the Partnership has changed over the years, to reflect the physician partners' names. A copy of the North Carolina General Warranty Deed to the property on which the facility is located, filed August

Lee B. Hoffman
April 12, 2004
Page 2

10, 1984, is attached hereto as Exhibit 2. As set forth therein, Richard D. Callahan, M.D. and Barton R. Paschal, M.D. were the two partners in the Partnership (as well as the two shareholders in the Practice) at that time. Over the years, the ownership interests in the two entities have changed, but the partners in the Partnership and the shareholders of the Practice remain the same. Those current owners are Barton R. Paschal, M.D., Don V. Jackson, M.D., James B. Puckett, M.D., and T. Mark Davis, M.D.

The Partnership has been the owner/lessor and the Practice has been the operator/less of the Facility since it opened in 1985. A copy of the Memorandum of Lease between the Partnership and the Practice is attached hereto as Exhibit 3.

Purchase of Real Estate and Construction of Facility

The real estate in question (hereinafter, the "Property") is approximately 0.71 acre, located at One Doctors Drive, Asheville, North Carolina, 28801. As shown by the Deed attached as Exhibit 2, It was purchased by the Partnership on August 10, 1984. Attached hereto as Exhibit 4 is a copy of the Closing Statement regarding this purchase. As set forth therein, the purchase price was \$43,500.00.

On July 9, 1985, the Partnership entered into a contract with H.M. Rice and Son, Inc., to construct the Facility. The contract amount was \$253,633.00. A copy of an Application and Certificate for Payment verifying the contract amount is attached hereto as Exhibit 5. In addition to the above, the Partnership incurred other capital expenses related to the construction of the Facility. These services included:

Subsurface exploration	\$1,136.50 (Exhibit 6 and 9);
Survey	\$750.00 (Exhibit 7 and 9);
Water and sewer hookup	\$480.00 + \$360.00=\$840.00 (Exhibits 8 and 9)
Recording fee	\$33.50 (Exhibits 4 and 9)
Title insurance	\$442.00 (Exhibits 4 and 9)
Legal fees	\$1,223.00 (Exhibits 4 and 9)
Origination fee	\$975.00 (Exhibits 4 and 9)
Appraisal fee	<u>\$100.00</u> (Exhibits 4 and 9)
TOTAL	<u>\$5,499.50</u>

The Facility was completed in 1985, and the Practice began practicing medical oncology therein.

In 1991, the Partnership and the Practice embarked on an expansion of the Facility. In this regard, the following contracts were executed and paid by the Partnership:

- J. Cole Construction Company, \$75,588.72 (copy of 2/12/92 final Application and Certificate of Payment attached hereto as Exhibit 10);
- ECM Corporation, \$7,857.00 (copies of 5/29/91 Proposal and 10/25/91 Invoice attached hereto as Exhibit 11);
- Ball Heating & Air Conditioning Co., Inc., \$5,500.00 (copies of 7/19/91 Proposal and 1/19/92 Invoice attached hereto as Exhibit 12);
- Dotson Plumbing & Heating Co., Inc. \$7,468.00 (copies of 5/28/91 Proposal and 1/25/92 Application for Payment attached hereto as Exhibit 13).

The total amount billed and paid on these contracts was \$96,413.72.

Attached hereto as Exhibit 14 is a copy of a plat, showing the Property and the site of both sections of the Facility constructed in 1985 and 1991-92.

Purchase of Medical Equipment

Since 1985, the Practice has provided professional services in the Facility to cancer patients, including the following:

- patient consultation;
- patient examination;
- medical oncology treatment;
- nutritional counseling; and
- patient screening, education, early detection and public awareness programs.

As part of the provision of these medical services, the Practice purchased medical equipment over the years. Our clients no longer have copies of invoices related to that equipment. However, in 1995, our clients entered into an agreement with US Oncology, whereby US Oncology would manage the Facility. As part of that agreement, the Practice prepared an inventory of all of its assets related the Facility. Included in that inventory is the medical equipment, and the date acquired. Based upon that inventory, as well as the recollection of employees of the Facility, we have determined that the following items of equipment (including month of purchase and purchase price) were owned by the Practice as of March 18, 1993.

- Gemstar Chemistry Analyzer - purchased November, 1986, \$9,500.00. This equipment is used to run chemistry profiles or individual tests.
- Serono-Baker Hematology Analyzer - purchased December 1989, \$30,566.19. This equipment is used for cell counts, indices, platelets, and three-part differential.
- Six-unit Manual Cell Counter, purchased January 1989, \$149.95.
- Biopharm hood, purchased September 12, 1989, \$3,286.80.

A copy of the asset inventory identifying this equipment is attached as Exhibit 15, with the equipment identified above highlighted. In addition, in August of 1992, the Practice leased from Roche Diagnostic Systems, Inc. laboratory equipment which had a total list price (and hence, fair market value) of \$94,700. A copy of that equipment lease is attached hereto as Exhibit 16.

Thus, the total fair market value and/or purchase price of medical equipment acquired and owned by the practice as of March 18, 1993 was \$138,202.94.

Discussion

The operative statute in this regard is N.C.Gen.Stat. §131E-176(18a), which defines an oncology treatment center as follows:

“Oncology treatment center” means a *facility, program, or provider*, other than an existing health service facility that provides services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceeds two hundred fifty thousand dollars (\$250,000). In determining whether costs are more than two hundred fifty thousand dollars (\$250,000), the costs of equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the facility, program, or provider 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 (emphasis added).

Based upon the above facts, the Partnership and the Provider are able to document that between 1984 and March 18, 1993, they incurred capital costs to acquire land and construct space totaling \$399,046.22, and acquired medical equipment in the amount of \$138,202.94, all for the provision of medical oncology treatment services, for a total capital cost of \$537,249.16. Therefore, the Partnership and the Practice collectively developed a “facility” which provided “services for diagnosis, evaluation, or treatment of cancer and its aftereffects or secondary results and for which the total cost of all the medical equipment utilized by the center, exceed[ed] two hundred fifty thousand dollars (\$250,000).” G.S. 131E-176(18a). These services have been continually provided at the Facility since 1985.

Conclusion

Based upon our research and analysis of the facts, the facility owned by Paschal and Jackson General Partnership, Lessor and operated Asheville Hematology and Oncology Associates, P.A., Lessee

Lee B. Hoffman
April 12, 2004
Page 5

is an oncology treatment center as defined in G.S. 131E-176(18a), and was prior to March 18, 1993. As you can see from the attached materials, the statutory prerequisites for meeting the definition of an oncology treatment center were in place prior to the amendment to the CON law in 1993. The Partnership and the Practice had purchased land, build a building and was utilizing medical equipment having a cost in excess of \$250,000, to provide medical oncology, hematology and laboratory services prior to March 18, 1993. Based upon our review of the facts and law related thereto, we believe that the Facility is a grandfathered oncology treatment center. We would appreciate you confirming that our analysis is correct and advising us as to what, if any, further steps our clients need to take to be properly recognized as an oncology treatment center by the State of North Carolina.

Please contact us if you have any questions or if you need any further information regarding this request.

Very truly yours,

BODE CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh: 4016.004
Enclosures



North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

June 25, 2004

S. Todd Hemphill
Bode, Call, & Stroupe
8105 Glenwood Avenue
PO Box 6338
Raleigh, NC 27628-6338

RE: Inquiry/ Status of Paschal, Jackson, Puckett and Davis General Partnership and Asheville Hematology and Oncology Associates, P.A. as an oncology treatment center /Buncombe County

Dear Mr. Hemphill:

In response to your letter of April 12, 2004, the Certificate of Need Section has determined that the above referenced partnership and practice, operating at One Doctors Drive, in Asheville, was an "oncology treatment center", as defined in N.C.G.S. 131E-176(18a), prior to March 18, 1993, because it provided services for diagnosis, evaluation, or treatment of cancer and its total cost of making the medical equipment and the facility operational, exceeded two hundred fifty thousand dollars (\$250,000).

It should be noted that this Agency's position is based solely on the facts represented by you and that any change in facts as represented would require further consideration by this Agency and a separate determination. If you have any questions concerning this matter, please feel free to contact this office.

Sincerely,

Ronald Loftin, Project Analyst

Lee B. Hoffman, Chief
Certificate of Need Section

cc: Tom Elkins, Medical Facilities Planning Section, DFS



STATE HEALTH COORDINATING COUNCIL

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Table 9E: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area #	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2009-9/30/2010	Average # of Procedures per Unit
Harris Regional Hospital	1	Jackson	1	3,890	3,890
NC Radiation Therapy - Franklin	1	Macon	1	1,481	1,481
Mission Hospitals	2	Buncombe	3	20,415	6,805
Cancer Centers of North Carolina-Asheville Hematology Oncology	2	Buncombe	1	2,016	2,016
NC Radiation Therapy - Asheville	2	Buncombe	2	7,641	3,821
NC Radiation Therapy - Clyde	2	Haywood	1	5,030	5,030
NC Radiation Therapy - Marion	2	McDowell	1	4,038	4,038
Watauga Hospital	3	Watauga	1	3,022	3,022
Margaret Pardee Memorial Hospital	4	Henderson	1	6,144	6,144
NC Radiation Therapy - Brevard	4	Transylvania	1	2,866	2,866
NC Radiation Therapy - Hendersonville	4	Henderson	1	105	105
Catawba Valley Medical Center	5	Catawba	2	12,930	6,465
Frye Regional Medical Center	5	Catawba	1	3,961	3,961
Valdese General Hospital	5	Burke	2	7,622	3,811
Caldwell Memorial Hospital	5	Caldwell	1	2,741	2,741
Cleveland Regional Medical Center	6	Cleveland	1	5,534	5,534
Gaston Memorial Hospital	6	Gaston	3	14,782	4,927
Lincoln Radiation Oncology Associates	6	Lincoln	I will be transferred from Gaston Memorial Hospital	NR	NR
NC Radiation Therapy - Forest City	6	Rutherford	1	5,529	5,529
Pineville Radiation Therapy Center	7	Mecklenburg	1	9,127	9,127
Carolinas Medical Center	7	Mecklenburg	3	16,393	5,464
Mathews Radiation Oncology	7	Mecklenburg	1	10,479	10,479
Presbyterian Hospital	7	Mecklenburg	4	13,773	3,443
University Radiation Oncology	7	Mecklenburg	1	6,628	6,628
CMC-Union	7	Union	1	7,035	7,035
Iredell Memorial Hospital	8	Iredell	2	6,087	3,044
Lake Norman Radiation Oncology Center	8	Iredell	1	9,190	9,190
Rowan Regional Medical Center	8	Rowan	1	5,967	5,967
CMC-NorthEast Medical Center	9	Cabarrus	2	11,810	5,905
Stanly Regional Medical Center	9	Stanly	1	4,290	4,290
Forsyth Memorial Hospital	10	Forsyth	4	27,242	6,811
N. C. Baptist Hospitals	10	Forsyth	4	17,945	4,486
Hugh Chatham Memorial Hospital	10	Surry	1	4,468	4,468
Cancer Center of Davidson County	11	Davidson	1	3,437	3,437
High Point Regional Health System	12	Guilford	2	8,282	4,141
Moses Cone Health System	12	Guilford	4	25,756	6,439
Morehead Memorial Hospital	12	Rockingham	1	5,680	5,680
Randolph Cancer Center	13	Randolph	1	4,160	4,160
UNC Hospitals [Approved for 1 linear accelerator on 2/07/2011 (J-008500-10) and another linear accelerator on 3/29/2011 (J-008611-10)]	14	Orange	6	30,238	5,040
Alamance Regional Medical Center	15	Alamance	2	9,504	4,752

Table 9E: Hospital and Free-Standing Linear Accelerators and Radiation Oncology Procedures

Facility Name	Service Area #	County	Number of Linear Accelerators	Number of Procedures (ESTVs) 10/1/2009-9/30/2010	Average # of Procedures per Unit
Duke University Hospital	16	Durham	8	34,771	4,346
Durham Regional Hospital	16	Durham	1	5,750	5,750
Maria Parham Hospital	16	Vance	1	6,642	6,642
FirstHealth Moore Regional	17	Moore	2	19,954	9,977
Scotland Memorial Hospital	17	Scotland	1	3,907	3,907
Cape Fear Valley Medical Center	18	Cumberland	5	19,668	3,934
Southeastern Regional Medical Center	18	Robeson	1	9,046	9,046
Sampson Regional Medical Center	18	Sampson	1	2,134	2,134
New Hanover Radiation Oncology	19	New Hanover	2	12,987	6,494
New Hanover Regional Medical Center	19	New Hanover	1	6,078	6,078
South Atlantic Radiation Oncology	19	Brunswick	1	4,838	4,838
Franklin County Cancer Center (included in inventory by letter of no review 5/09/2011)	20	Franklin	1	NR	NR
Raleigh Hematology Oncology Associates/Cancer Centers of NC	20	Wake	2	11,506	5,753
Duke Raleigh Hospital	20	Wake	1	7,572	7,572
Rex Hospital	20	Wake	4	19,636	4,909
Wake Radiology / Oncology Services	20	Wake	1	5,633	5,633
Rex Healthcare (Smithfield Radiation Oncology)	21	Johnston	1	3,015	3,015
Johnston Radiation Oncology dba Clayton Radiation Oncology	21	Johnston	1	863	863
Lenoir Memorial	22	Lenoir	1	5,041	5,041
Goldsboro Radiation Therapy Services dba Wayne Radiation Oncology Center	22	Wayne	1	5,269	5,269
Carteret General Hospital	23	Carteret	1	4,319	4,319
CarolinaEast Medical Center	23	Craven	2	8,353	4,177
Onslow Radiation Oncology	24	Onslow	1	NR	NR
Nash Day Hospital	25	Nash	2	8,174	4,087
Roanoke Valley Cancer Center	25	Halifax	1	3,278	3,278
Wilson Medical Center	25	Wilson	1	5,407	5,407
Beaufort County Hospital	26	Beaufort	1	3,458	3,458
Ahoskie Cancer Center	26	Hertford	1	2,199	2,199
NC Radiation Therapy Management Services (prev Carolina Radiation Medicine, P.A.)	26	Pitt	1	10,705	10,705
ECU Brody School of Medicine [On 12/30/2010 related entity NewCo Cancer Services acquired 2 existing linear accelerators (Q-008562-10) and Pitt County Memorial Hospital acquired 1 existing linear accelerator (Q-008558-10)]	26	Pitt	3	14,512	4,837
Albemarle Hospital	27	Pasquotank	1	5,426	5,426
Alliance Oncology dba Outer Banks Cancer Center	27	Dare	1	3,370	3,370
TOTALS (72 Facilities)			122	600,749	4,924

BODE, CALL & STROUPE, L.L.P.

ATTORNEYS AT LAW

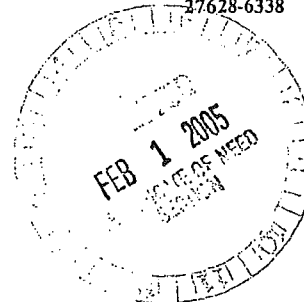
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February 1, 2005

Hand DeliveryLee B. Hoffman, Chief
Ronald Loftin, Project Analyst
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Asheville, North Carolina 27603

Re: Asheville Hematology and Oncology Associates, P.A./Relocation and Equipment
Acquisition No Review Request

Dear Ms. Hoffman and Mr. Loftin:

We represent Paschal, Jackson, Puckett and Davis General Partnership (hereinafter, the "Partnership") and Asheville Hematology and Oncology Associates, P.A. (hereinafter, "Asheville Hematology"). Asheville Hematology is a North Carolina professional corporation, which was formed in 1982, to engage in the practice of medical oncology. The Partnership is a North Carolina General Partnership which was formed in 1984 by the physician owners of Asheville Hematology, to purchase real estate in Asheville, Buncombe County, construct a building for a medical oncology practice (hereinafter the "Facility"), and lease the Facility to Asheville Hematology. The Facility is located at One Doctors Drive, Asheville, North Carolina, 28801. Last year, we submitted a request asking you to determine that the Facility owned by the Partnership and operated by Asheville Hematology was a grandfathered oncology treatment center, within the meaning of the CON law. By letter dated June 25, 2004, you issued that determination.

Asheville Hematology has now entered into a tentative agreement with Centex Development Company ("Centex")¹ to relocate the Facility in leased space in a new building to be constructed by Centex in Asheville, North Carolina. Centex and Asheville Hematology intend to locate the facility at Lot 10, Sweeten Creek Road, Asheville, North Carolina, approximately three to four miles from the

¹ Centex is not related by common ownership to Asheville Hematology or its management company, US Oncology. Centex's sole benefit from this project will be the rental payments associated with leasing space.

Facility's current location. Asheville Hematology will lease its space pursuant to an operating lease. The cost of acquiring the site and constructing the building will be borne by Centex.

Asheville Hematology also intends to purchase a linear accelerator, a CT scanner, and treatment planning equipment, which will be installed during the upfit of the leased space. The equipment will be placed on line at the same time that the oncology treatment center is moved. As set forth in more detail below, Asheville Hematology will bear the cost for the upfit of space to the extent that such upfit is essential to the operation of the medical equipment to be acquired. All other construction costs not directly attributable to the installation and operation of this equipment will be part of the developer's base costs.

We have been requested by Asheville Hematology to request that you confirm that the relocation of the existing oncology treatment center,² and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, is not a new institutional health service, within the meaning of the CON law.

Calculation of Space Attributable to Each Service

To assist you in understanding what space has been attributed to each aspect of the project, we have enclosed as Exhibit 1 a line drawing of the entire space. The entire space on Exhibit 1 is the relocated oncology treatment center. Within that facility, following are the spaces related to the equipment described above:

Linear Accelerator

Vault	1,705 sq.ft.
Control room	180 sq.ft.
Mold Room	108 sq.ft.
Mechanical room	<u>174 sq.ft.</u>
TOTAL	2,167 sq.ft.

2A, 133 GSF

9% of Total Gross

CT Scanner

CT room	504 sq.ft.
Control room	135 sq.ft.
Dark room	<u>81 sq.ft.</u>
TOTAL	720 sq.ft. ³

3% of Total Gross

² Because the Partnership will no longer be the lessor of the Facility upon relocation, the Partnership recognizes that the relocation will terminate its separate ownership of the oncology treatment center, and that Asheville Hematology will be the sole holder of the right to operate the oncology treatment center.

³ There also is a 54 sq.ft. rest room attached to the CT scanner room, as a convenience to patients. Per our discussions related to a previous review of a similar facility, you advised that this space need not be included in the cost calculation for the CT scanner, since it is not essential to the operation of that equipment.

*.75% of Total
Gross*

Treatment Planning Equipment

Treatment planning room 180 sq.ft.

Calculation of Developer's Base Costs

Throughout the calculations in this letter and the attachments, the developer's base cost for constructing the building are not included in the costs associated with the relocation of the oncology treatment center or the acquisition of the equipment described herein. The developer's base costs related to its construction of the building are included in a separate column in Exhibit 2.⁴ Developer's base cost is the cost which the developer will incur to build a basic medical office building. Only where such cost can be directly attributed to upfit of space that is necessary to make the equipment or health service operational, has that cost been attributed to the service.

This is true for space related to the linear accelerator, the treatment planning room, the CT scanner room and the medical oncology space. To the extent that each of those spaces is general office space, hard and soft costs are attributed to the developer's base costs. Only those additional upfit and related costs directly related to making either the equipment or the medical service operational are attributed to the cost thresholds. Where there are soft costs related to that upfit, they have been included in the calculation.

Acquisition and Installation of Linear Accelerator

The question of whether an existing oncology treatment center may acquire a linear accelerator without a certificate of need turns upon whether the linear accelerator is major medical equipment, within the meaning of the CON law. "Major medical equipment" means

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...

G.S. 131E-176(14f). Here, the linear accelerator is not major medical equipment, because the cost to acquire and make operational that equipment does not exceed \$750,000. As set forth in the certified capital cost form attached as Exhibit 2, the total cost associated with the linear accelerator will be \$743,039. We also have included a breakdown of all of the costs for each space related to the operation of the linear accelerator. The assumptions associated with the breakdown of capital costs for the project are at the end of Exhibit 2.

⁴ Some total amounts in Exhibit 2 may vary slightly from those in this letter, due to rounding.

As set forth at the beginning of Exhibit 2, the capital cost form is certified by John L. Thompson, Jr., AIA, a licensed North Carolina architect. The actual cost of the linear accelerator and related movable and fixed equipment, together with physics commissioning, is \$380,685, and is broken out in further detail in the chart attached as Exhibit 3 and the vendor quotes attached as Exhibit 4.⁵ Construction and other allocated costs totaling \$362,354 are further broken down in Exhibit 5.

The space which is necessary to make the linear accelerator operational is comprised of the vault, the control room, the mold room, and the mechanical room. Because the vault is a unique space, which has no other practical purpose, all of the "hard" construction costs related to that space were included in Exhibit 2. In addition, estimated "soft" construction costs, such as architect and engineering fees, bonds, permits, etc., were included in the cost of radiation oncology.

With regard to the control room, mold room and mechanical room, unlike the vault, these are simply general office space, with some additional upfit related to the operation of the linear accelerator. The costs attributed to the linear accelerator are the hard and soft costs related to the upfit of those spaces necessary to operate the linear accelerator. For instance, the mechanical room will require the installation of a chiller, to ensure that the linear accelerator does not overheat. Additional HVAC and electrical upgrades will be necessary, which have been included in the costs attributable to the linear accelerator. All equipment in these rooms essential to the operation of the linear accelerator is included.

Because Asheville Hematology's cost to acquire and make operational the linear accelerator does not exceed \$750,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Acquisition of CT Scanner

As with the linear accelerator, the question of whether the acquisition of CT scanner would require a CON turns on the question of whether it is major medical equipment. In addition, because a CT scanner is medical diagnostic equipment, the statute related to diagnostic centers comes into play.

"Diagnostic center" means a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten

⁵ The quotes included are for pieces of equipment to be purchased that are greater than \$1,000, as well as a few quotes for individual pieces of equipment that add up to over \$1,000. Costs for new equipment valued at less than \$1,000 are based on US Oncology experience. Included with the quotes in Exhibit 4 is a price list from Standard Imaging for various types of equipment. Only those items checked will be purchased. In addition, certain items of used equipment identified in Exhibit 3 are currently owned by US Oncology, and will be transferred from facilities that have been recently closed. US Oncology has estimated their fair market value in the chart attached as Exhibit 3. No sales tax has been included for that equipment, as there will be none.

thousand dollars (\$10,000) or more exceeds five hundred thousand dollars (\$500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the 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.

G.S. 131E-176(7a).

Asheville Hematology is not a diagnostic center. Therefore, in order to acquire a CT scanner (which would be the only medical diagnostic equipment owned or operated by Asheville Hematology) without CON review, the cost of acquiring and making that equipment operational may not exceed \$500,000.

As set forth in the certified capital cost form attached as Exhibit 2 the total cost associated with the CT Scanner will be \$485,170. The actual cost of the CT scanner and related equipment is \$442,447, and is broken out in further detail in the chart attached as Exhibit 6 and the vendor quotes attached as Exhibit 7. The construction and other allocated costs associated with the CT scanner are \$42,723, and the construction costs reflect the actual cost to upfit the space identified, in order for it to be used as a CT room. The shell space for the room in which the CT scanner will be located is not included, because that construction will be borne by the developer, and will be no different than construction related to general office space. In addition, there are no additional upfit costs related to the control room and dark room.⁶ Attached as Exhibit 8 is a chart showing a break-out of the projected costs associated with the upfit of the CT room for the above project, as set forth in Exhibit 2.

Because Asheville Hematology's cost to acquire and make operational the CT scanner does not exceed \$500,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Acquisition of Treatment Planning Equipment

As with the linear accelerator, the question of whether the acquisition of treatment planning equipment would require a CON turns on the question of whether it is major medical equipment. As set forth in the certified capital cost form attached as Exhibit 2, the total cost associated with the treatment planning equipment will be \$147,758. The actual cost of the treatment planning computer and related simulation software is broken out in further detail in the chart attached as Exhibit 9. The vendor quote for the treatment planning hardware is included in the quote for the linear accelerator, Exhibit 4. The simulation hardware and software quote is contained in Exhibit 10. There is no construction cost associated with the installation of the treatment planning equipment, because the developer will bear the

⁶ As a practical matter, the dark room will not be necessary to operate the CT scanner as a simulator, since CT simulation is performed digitally. The dark room would only be necessary for developing film for diagnostic scans.

cost of building the shell space, and no special construction (such as shielding or additional electrical requirements) is required to operate this equipment. The only additional cost associated with the treatment planning equipment are the legal fees related to this request.

Because Asheville Hematology's cost to acquire and make operational the treatment planning equipment does not exceed \$750,000, it is our opinion that the acquisition of that equipment is not a new institutional health service and that a no review letter can be issued for that acquisition.

Relocation of Oncology Treatment Center

With regard to the relocation of the oncology treatment center, the only issue involved is whether the capital costs associated with that relocation will cost in excess of \$2,000,000. According to G.S. 131E-176(b), included among new institutional health services is

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).

As set forth in the certified capital cost form attached hereto as Exhibit 2, Asheville Hematology's total capital costs related to the relocation of the oncology treatment center, unrelated to the acquisition and installation of the above equipment, will be \$364,301. The actual cost of the equipment to be acquired for the relocated oncology treatment center is \$311,679, and is broken out in further detail in the vendor quotes attached as Exhibit 11 and the chart attached as Exhibit 12. Construction, equipment and other costs related to relocating the oncology treatment center are itemized in Exhibit 12. All other construction costs are included in the developer's base cost to build a basic medical office building.

Conclusion

Based on the above, the combination of the costs related to the acquisition of the linear accelerator (\$743,039), the acquisition of the CT scanner (\$485,170), the acquisition of treatment planning equipment (\$147,758) and the relocation of the oncology treatment center (\$364,301), totals \$1,758,267, well below the \$2,000,000 threshold. Therefore, the relocation of the oncology treatment center is not a new institutional health service within the meaning of the CON law.

We have enclosed with this letter an exhibit notebook which contains the following:

1. Line drawing of new office space;
2. Cancer Center cost breakdown chart, with letter from John L. Thompson, Jr., licensed architect, certifying construction costs;

3. Equipment cost breakdown, linear accelerator and miscellaneous radiation therapy equipment;
4. Vendor quotes, linear accelerator, treatment planning hardware and miscellaneous radiation therapy equipment;
5. Linear accelerator construction cost estimate breakdown;
6. Equipment cost breakdown, CT scanner and related equipment;
7. Vendor quotes, CT scanner and related equipment;
8. CT construction cost estimate breakdown;
9. Equipment cost breakdown, treatment planning equipment;
10. Vendor quote for simulation hardware and software;
11. Vendor quotes, miscellaneous oncology treatment center medical equipment;
12. Relocated oncology treatment center construction cost estimate breakdown.

We respectfully request that you review the attached documentation and provide us at your earliest convenience with a no review letter stating that the relocation of the existing oncology treatment center and physician office, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, do not require certificate of need review and are not new institutional health services, within the meaning of the CON law.

Please let me know if you need further information or if there are questions I can answer. I look forward to hearing from you at your earliest convenience.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh
Enclosures

BODE, CALL & STROUPE, L.L.P.

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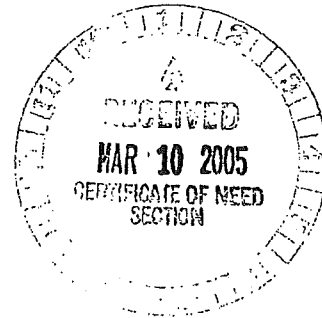
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March 10, 2005

Hand Delivery

Ronald Loftin, Project Analyst
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603



Re: Asheville Hematology and Oncology Associates, P.A./Relocation and Equipment
Acquisition No Review Request

Dear Mr. Loftin:

We have reviewed Ms. Amy Bason's February 18, 2005 letter submitted to you on behalf of Asheville Radiology Associates, P.A. ("ARA"), challenging the information set forth to you in our February 3, 2005 letter related to the acquisition of certain medical equipment by our client, Asheville Hematology and Oncology Associates, P.A. (hereinafter, "Asheville Hematology"). Ms. Bason's letter appears to disregard both the clear language of the CON laws related to the equipment at issue, as well as the Agency's prior interpretation of those laws. We will address each of ARA's contentions in turn.

1. The proposed linear accelerator constitutes major medical equipment.

This contention essentially argues that the linear accelerator, treatment planning equipment and CT simulator discussed in our February 3, 2005 letter should be considered as a "single system of components" for determining whether the linear accelerator fits within the definition of major medical equipment under G.S. 131E-176(14f), because all are used in the provision of radiation therapy services. This contention directly conflicts with the Agency's prior interpretations of the CON law as it applies to major medical equipment, and would produce absurd results. As the Agency is aware, treatment planning

and simulation can be and is done off site.¹ That being the case, neither the treatment planning equipment nor the simulator is essential to making the linear accelerator operational, within the meaning of G.S. 131E-176(14f), and therefore, should not be included in determining whether the linear accelerator is major medical equipment. Ms. Hoffman has confirmed this interpretation of the law in prior discussions.

The major medical equipment statute's use of the term "single unit or single system of components" is meant to address equipment which is an essential component of the equipment at issue. For instance, the equipment in the control room for the linear accelerator is part of and hence essential to the operation of the linear accelerator, even though it is in a separate room. Thus, the linear accelerator and the control room equipment constitute a "single system of components."

We are aware of several no review determinations by the CON Section,² consistently applying the CON law in a similar fashion regarding the acquisition of a linear accelerator and related equipment by a hospital or oncology treatment center, as follows:

- Scotland Memorial Hospital, no review letter issued October 14, 2002;
- Raleigh Hematology Oncology Associates, P.C., no review letter issued March 11, 2004;
- Sampson Regional Medical Center, no review issued pursuant to Settlement Agreement approved May 4, 2004, in contested case no. 03 DHR 1714;
- Lake Norman Radiation Oncology, LLC, no review letter issued September 30, 2004;
- Caldwell Memorial Hospital, no review letter issued February 9, 2005.

2. The proposed CT scanner constitutes establishment of a diagnostic center.

ARA's argument in this regard is that the treatment planning equipment also should be considered to be medical diagnostic equipment in determining whether the facility is a diagnostic center, because it might be used in conjunction with the CT scanner. Again, this interpretation of the CON law is inconsistent with the Agency's prior interpretation of the law, as well as the CON law's definition of diagnostic center, which requires an examination of the costs essential to making operational the equipment at issue. G.S. 131E-176(7a). Here, the treatment planning equipment is not medical diagnostic equipment, and is not essential to making the CT scanner operational, and therefore should not be considered in determining whether the facility is a diagnostic center.

In this regard, the definitions of major medical equipment and diagnostic center differ from the definition of an oncology treatment center. In determining costs for determining whether a facility is an oncology treatment center, the CON law looks at costs "essential to acquiring and making operational the facility, program, or provider...." G.S. 131E-176(18a). Conversely, in determining the cost of whether a

¹ The Scotland Memorial Hospital proposal discussed below specifically proposed that treatment planning and simulation would be done at a site other than the Hospital.

² We have no doubt that there are other such determinations of which we are not aware.

facility is a diagnostic center or whether medical equipment constitutes major medical equipment, the CON law considers the costs "essential to acquiring and making operational the ... equipment...." G.S. 131E-176(7a), (14f). Had Asheville Hematology been proposing to develop a radiation oncology facility under the \$250,000 threshold for oncology treatment centers, then Ms. Bason's arguments might have some merit. However, since Asheville Hematology already is a grandfathered oncology treatment center, that statute does not apply for determining the cost of the equipment to be acquired.

There also seems to be some confusion on ARA's part to the effect that there is a CT simulator which is different from the CT scanner at issue. That is the same piece of equipment, so there is no additional cost. Therefore, the only equipment at issue with regard to the definition of a diagnostic center is the CT scanner, and its cost does not exceed \$500,000.

3. The proposed equipment may be used together to constitute IGRT or IMRT.

The equipment identified in our prior letter does not include these services. However, even if it did, it would be irrelevant, as it would not change the fact that it is inappropriate under the CON law to combine separate pieces of medical equipment to create one item of major medical equipment. As the Agency has previously found, the fact that the CT simulator and the treatment planning equipment may be used to assist in radiation therapy does not mean that either piece of equipment is essential to making the linear accelerator operational. That being the case, these items of equipment may not be combined when determining the application of the major medical equipment statute.

4. Calculations of square footage attributable to each service may be underestimated.

Our client very carefully reviewed the plans for the proposed facility prior to submitting its no review request, and included in its calculations of proposed costs all space which is essential to the operation of the linear accelerator, the CT scanner and the treatment planning equipment. The electrical room and the bio-hazard room are not essential to the operation of the linear accelerator, and the view room is not essential to the operation of the CT scanner.³ Therefore, their costs have no relation to the cost of that equipment.

5. Change in ownership

The owners of Paschal, Jackson, Puckett and Davis General Partnership and the owners of Asheville Hematology are the same individuals. Therefore, there effectively is no change of ownership. See 10A N.C.A.C. 14C.0502(b). In addition, G.S. 131E-189(c) is wholly inapplicable, as it relates only to the transfer of facilities developed pursuant to a certificate of need. Since neither Paschal, Jackson, Puckett and Davis General Partnership nor Asheville Hematology filed a CON application or received a CON, there are no "representations made in the application" and no "conditions ...placed on the

³ Also, there are no special upfit costs for these rooms, those costs will be borne by the developer, and there is no medical diagnostic equipment in those rooms within the meaning of G.S. 131E-176(7a).

Mr. Loftin
March 10, 2005
Page 4

'certificate of need" with which either must comply, and more important, no CON to transfer, within the meaning of G.S. 131E-189(c).

Finally, to the extent that the Partnership's relinquishment of its CON rights in the oncology treatment center would constitute the transfer of the health service facility to Asheville Hematology, that is permitted under G.S. 131E-184(a)(8) without a certificate of need, so long as prior written notice is given. Our February 3, 2005 letter to you provided such prior notice.

For the above reasons, we believe that the comments submitted on behalf of ARA are incorrect, immaterial and inconsistent with the CON law and the Agency's interpretations thereof. We request that the Agency proceed at its earliest convenience to provide Asheville Hematology with a no review letter stating that the relocation of the existing oncology treatment center and physician office, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, do not require certificate of need review and are not new institutional health services, within the meaning of the CON law.

Thank you very much for your attention to this matter.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh



North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section
2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
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Lee Hoffman, Section Chief
Phone: 919-855-3873
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June 6, 2005

S. Todd Hemphill
Bode, Call & Stroupe, LLP
PO Box 6338
Raleigh, NC 27628-6338

RE: Information Required for No Review Determination/ Asheville Hematology and Oncology Associates, PA/
Acquisition of linear accelerator, CT simulator and treatment planning equipment/ Buncombe County

Dear Mr. Hemphill:

The Certificate of Need (CON) Section has received your request for a determination as to whether the above mentioned project requires a certificate of need. In order for the CON Section to make such a determination, please submit the following information to this office:

1. State all assumptions and legal bases on which you relied to conclude, "the electrical room and bio-hazard room are not essential to the operation of the linear accelerator." Describe all functions of these rooms and provide the number of square feet in each room.
2. State all assumptions and legal bases on which you relied to conclude, "the view room is not essential to the operation of the CT scanner." Describe all functions of this room and the number of square feet in the room.
3. Your letter states "there are no special upfit costs for these rooms, those costs will be borne by the developer..." Identify and describe all costs you state will be borne by the developer for development of each of the three rooms referenced above.
4. Identify and provide the costs of all equipment located in each of the same three rooms.
5. Identify the record and verify system to be used for the linear accelerator (e.g. IMPAC, Varis). Provide the costs for the workstation and hardware and software to be used for this purpose. Document that these costs are included in the projected costs for the linear accelerator.
6. The quotation for the "Eclipse DX Workstation" includes "2-D BrachyVision" software. Provide all costs for development of brachytherapy treatment services including costs of equipment and related activities, in accordance with 15A NCAC 11 .0700 and .0322.
7. In accordance with G.S.131E-176(16)b., document that all costs for "staff effort and consulting and other services, essential to the acquisition, improvement, expansion, or replacement" of the existing oncology treatment center are included in the total capital expenditure for the project, e.g. Asheville Hematology and Oncology Associates, P.A.'s staff costs related to development of the proposed project.

If you have any questions regarding this matter, please feel free to contact this office.

Sincerely,

Lee B. Hoffman, Chief
Certificate of Need Section



BODE, CALL & STROUPE, L.L.P.

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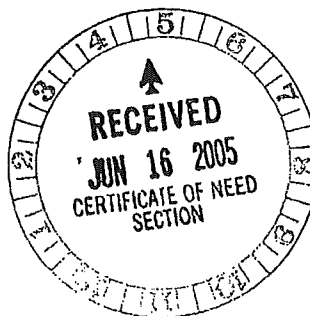
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June 16, 2005



Hand Delivery

✓ Lee B. Hoffman, Chief
Ronald Loftin, Project Analyst
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Asheville Hematology and Oncology Associates, P.A./Relocation and Equipment Acquisition No Review Request

Dear Ms. Hoffman and Mr. Loftin:

This letter is in response to Ms. Hoffman's June 6, 2005 letter, raising additional questions related to the above matter. The questions and our responses are set forth below.

1. **State all assumptions and legal bases on which you relied to conclude, "the electrical room and bio-hazard room are not essential to the operations of the linear accelerator." Describe all functions of these rooms and provide the number of square feet in each room.**

Electrical Room (108 sq. ft): The purpose of the electrical room is to house the equipment that distributes electrical power throughout all areas (both internal and external) of the oncology center. This is a standard room, with no additional expense attributable to the linear accelerator. In fact, if the linear accelerator were not part of the project, the cost of the electrical room would be the same.

The electrical service and disconnect panel specific to the linear accelerator is not located in the electrical room, but rather, on the vault wall behind the control desk. The cost of this panel has been recognized in the cost of the construction of the vault. It is identified as "Misc Elec for equip" (\$10,000) in the Linear Accelerator Cost Estimate Breakdown attached as Exhibit 5 to our February 1, 2005 letter to you.

The construction of the electrical room is part of the developer's base cost. It would be difficult to calculate the cost of construction of one room, since costs can vary based on the specifications for a particular space. However, a reasonable average construction cost per square foot can be obtained by dividing the total developer's base cost from Exhibit 2 to our February 1, 2005 letter (\$4,167,814), by the total facility square footage of the facility, less the square footage of the linear accelerator vault (24,133 sq.ft - 1,705 sq.ft. = 22,428 sq.ft.).¹ This gives a cost per square foot of \$185.83. Using that cost per square foot, the cost of the electrical room would be as follows:

Electrical room size: 108 sq.ft.
Total cost: \$20,069.64 (108 sq.ft. x \$185.83/sq.ft.)

Biohazard Room: The purpose of the biohazard room is to provide a designated room for biohazard items, such as discarded medical supplies, chemotherapy drugs utilized by medical oncology, soiled linens, etc. This room provides ancillary support to the clinical operations of the oncology center but is not required for the operation of the linear accelerator.

As with the electrical room, this is a standard room, with no additional expense attributable to the linear accelerator, and if the linear accelerator were not part of the project, the cost of this room would be the same.

Biohazard room size: 72 sq.ft.
Cost: \$13,379.76 (72 sq.ft. x \$185.83/sq.ft.)

- 2. State all assumptions and legal bases on which you relied to conclude, "the view room is not essential to the operations of the CT Scanner." Describe all functions of this room and the number of square in the room.**

View Room: The view room is utilized principally by physicians and clinical staff to view images obtained on numerous devices and to consult with each other and patients. These images will primarily include external studies (such as MRI, PET, CT and bone scans) brought to the center by patients during their consultations.

In addition, Asheville Hematology's scanner can be used to perform diagnostic studies as deemed medically necessary by the medical staff. However, once the diagnostic study is completed, the images are burned onto a disk from the operator console (the cost of which is included in the cost of the CT scanner) and sent to an outside radiology group for diagnostic interpretations via a courier service. Since the reading of these diagnostic images must be performed by an outside

¹ The total square footage and the square footage of the vault are identified in the line drawing in Exhibit 1 to our February 1, 2005 letter. The square footage of the vault has been removed from the calculation, because all costs of construction of that space were included in our client's costs related to the acquisition of the linear accelerator. Including it in the developer's base costs would result in double-counting that space (and decreasing the developer's base cost per square foot).

radiologist, the view room is not needed to the extent that diagnostic studies are performed on the facility's CT.

The primary purpose of the CT scanner will be to acquire CT images for treatment planning simulator purposes. Once the initial images are acquired, the CT data set is electronically transmitted to the simulation workstation located in the treatment planning room. Therefore, the view room will not be used for the simulation process.

For these reasons, the view room is not essential to the operation of the CT scanner.

View room size: 108 sq.ft.
Cost: \$20,069.64 (108 sq.ft. x \$185.83/sq.ft.)

3. **Your letter states "there are not special upfit costs for these rooms, those costs will be borne by the developer..." Identify and describe all costs you state will be borne by the developer for the development of each of the three rooms referenced above.**

As noted above, there are no special requirements for the electrical room, the biohazard room and the view room. Their construction is no different than an office or a general work area, and they would have been included (and the cost would be the same) even if the linear accelerator and the CT were not going to be acquired. In response to your question regarding those costs, as discussed in more detail above, our client has estimated average construction cost per square foot of these rooms by dividing the total developer's base cost (\$4,167,814), by the total facility square footage of the facility, less the square footage of the linear accelerator vault (24,133 sq.ft - 1,705 sq.ft. = 22,428 sq.ft.), for a total cost of \$185.83/sq.ft.

4. **Identify and provide all cost of all equipment located in each of the three rooms.²**

Electrical Room: No equipment, only electrical distribution panels with circuit breakers, which are classified as fixtures. The total cost of these panels is \$12,000.

Biohazard Room: No equipment.

View Room: No clinical equipment, only wall mounted view boxes, the total cost of which is \$1,500.

² As discussed above, these rooms would be included in the building even if the linear accelerator and CT scanner were not acquired. Consequently, although their costs will be borne by the developer, if Asheville Hematology were responsible for these costs, they would only be attributable to the overall \$2,000,000 cost of relocating the oncology treatment center. As set forth in our prior letter, that total cost is only \$1,758,267. Even if one were to add all of the above construction and equipment costs related to the electrical room, biohazard room and view room, the total cost to relocate the center still would not exceed \$2,000,000.

- 5. Identify the record and verify system to be used for the linear accelerator (e.g. IMPAC, Varis). Provide the costs for the workstations and hardware and software to be used for this purpose. Document that these costs are included in the projected costs for the linear accelerator.**

When treating patients with radiation on a linear accelerator, the use of a record and verify system serves as an optional component of a quality control system for the radiation therapists. The record and verify system provides electronic validation of the daily treatment parameters but is not necessary in administration of radiation therapy. As such, it is not essential to the operation of the linear accelerator. At most, it is an optional part of the treatment planning system, which is a separate piece of medical equipment, as set forth in our February 1, 2005 letter, pages 5-6.³

Asheville Hematology intends to choose IMPAC to use as a record and verify system, and will pay a monthly subscription fee determined by the applications selected. The subscription fee covers the cost of hardware, software, telecommunication, maintenance and software upgrades. Additionally, the fee comes with an uptime and other service level guarantees. This model provides oncology centers the benefits of the IMPAC system without having to install, configure, maintain and upgrade an internal information system. Through this remote support configuration, IMPAC provides secure data off site backup, software and hardware upgrades as well as enhanced service support.

ASP subscription fee: \$9,505 monthly for a 60-month period. If purchased rather than leased, the cost of the equipment and computer software license would be approximately \$230,000.⁴

- 6. The quotation for the "Eclipse DX Workstation" includes "2-D BrachyVision" vision. Provide all costs for development of Brachytherapy treatment services including costs of equipment and related activities, in accordance with 15A NCAC11.0700 and .0322.**

The Varian Eclipse DX software and workstation quote that was submitted does include 2-D BrachyVision module as part of Varian's standard package. However, Asheville Hematology will not be offering brachytherapy services. In fact, in order to do so, Asheville Hematology would be required to purchase additional equipment and computer software, which is not included in the equipment to be purchased. Because brachytherapy will not be provided, the above rules are not applicable.

³ Asheville Hematology can operate the treatment planning system without this record and verify system. In fact, only 74 of the 94 radiation sites US Oncology manages have chosen to install a record and verify system.

⁴ The total projected cost of the treatment planning equipment set forth in our February 1, 2005 letter is \$147,758. Therefore, adding the \$230,000 fair market value of the IMPAC record and verify system would not cause the total cost of treatment planning equipment to exceed \$750,000.

7. In accordance with G.S. 131B-176(16) b., document that all costs for the "staff effort and consulting and other services, essential to the acquisitions, improvements, expansion, or replacement: of the existing oncology treatment center are included in the total capital expenditure for the project, e.g. Asheville Hematology and Oncology Associates, P.A.'s staff cost related to development of the proposed project.

Asheville Hematology staff time related to the development of this project was minimal, and neither staff time nor staff salaries are not accounted for based on the type of work involved. The only significant involvement by Asheville Hematology staff would have been the physician owners' time spent reviewing plans and deciding to approve the project. That would have been done on the physicians' own personal time.

We believe that the above addresses all of the questions you have raised. Given the amount of time since we originally submitted our request, we request that the Agency proceed at its earliest convenience to provide Asheville Hematology with a no review letter stating that the relocation of the existing oncology treatment center and physician office, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, do not require certificate of need review and are not new institutional health services, within the meaning of the CON law.

Thank you very much for your prompt attention to this matter.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

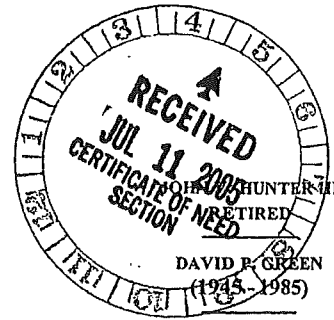
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July 11, 2005

Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Asheville Hematology and Oncology Associates, P.A./Relocation and Equipment
Acquisition No Review Request

Dear Ms. Hoffman:

You have requested additional information regarding the following question in your June 6, 2005 letter:

In accordance with G.S. 131B-176(16) b., document that all costs for the "staff effort and consulting and other services, essential to the acquisitions, improvements, expansion, or replacement: of the existing oncology treatment center are included in the total capital expenditure for the project; e.g. Asheville Hematology and Oncology Associates, P.A.'s staff cost related to development of the proposed project.

Following is a chart showing the total number of hours spent by Asheville Hematology and US Oncology employees, and an estimate of the total cost of these employees if each individual's salary was broken out into an hourly rate. US Oncology employees' salaries are confidential personnel information, which are not even shared among employees. For that reason, we have not listed what the hourly rate of each individual would be, or the product of the employee's time and that hourly rate.

Name	Position	# of hours applied to project	Hourly Rate ¹	Total
Bart Paschal, M.D.	Founder of Asheville Hematology & Oncology, P.A.	5		
Catherine Langford	East Region Director – Cancer Center Services, US Oncology	51		
William Herman	VP/GM Cancer Center Services, US Oncology	30		
Jim Carrier, Pharm D	Executive Director, NC, US Oncology	5		
Al Hirschler	Construction Operations, US Oncology	83		
Julie Fowler	Project Design Manager, US Oncology	39		
Jamie Belton	Facility Support Specialist, US Oncology	3		
Mike Wallendal	Construction Project Manager, US Oncology	1		
TOTAL		217	\$78.85	\$17,110.49

Please note that all of the hours listed on this chart are estimates. Further, because all of the US Oncology employees listed are salaried employees, they would have been paid irrespective of the time spent on this project. In addition, the time Dr. Paschal spent on the project was his own personal time, for which no compensation was given. For these reasons, we do not believe that this time properly should be included in the \$2,000,000 cost of the project, because there was no cost to Asheville Hematology for this staff effort within the meaning of G.S. 131B-176(16)b. Nevertheless, in an effort to resolve this matter expeditiously, we are providing this information.

As set forth in my February 1, 2005 letter, the total projected cost of the project is \$1,758,267. The addition of the \$17,110.49 of “staff effort” listed in the attachment hereto does not cause the cost of the project to exceed \$2,000,000. Therefore, we believe the fact remains that this project does not require a certificate of need.

In addition, you have inquired as to whether there is any interrelationship among the software involved for the CT simulator, the treatment planning equipment, and the linear accelerator, such that the cost of such software should be determined to be “essential” for the operation of equipment in whose category it has not previously been placed. Our client’s short answer to this is no. Each piece of equipment can be operated separately, and off site. For instance, the linear accelerator which Asheville Hematology is acquiring does not require on-site treatment planning equipment (or software) to perform radiation therapy. Both CT simulation and treatment planning could be performed off site, and the treatment planning equipment and software would be fully functional even if CT simulation were performed off site.

¹ The average total hourly rate was calculated by dividing the total cost by the total hours expended.

Ms. Hoffman
July 11, 2005
Page 3

To assist you in understanding the role of the various processes involved in radiation oncology, our client has prepared a Radiation Oncology Overview, which is attached hereto. It includes a discussion of the roles of various members of the radiation oncology team, a flow chart showing the process a radiation patient will go through, and an explanation of the clinical equipment associated with the radiation therapy process. Please note in that explanation that while the CT simulation and treatment planning software could be operated as part of one unit, it is not in the case of Asheville Hematology.

Furthermore, although the CT simulation software is not essential to the operation of the treatment planning software and hardware, even if it were, the combined cost would not exceed the CON cost threshold for major medical equipment. As set forth in my February 1, 2005 letter, the cost of the CT simulator and related equipment and software is \$485,170. The cost of the treatment planning hardware and software is \$147,758. The combined cost of that equipment is less than \$750,000, so even if one were to argue that the CT simulator and software are essential to the operation of the treatment planning equipment, the total cost would not make that equipment major medical equipment.²

I hope that this information satisfies all of your concerns. We would appreciate your prompt response to this latest information, and that the Agency proceed at its earliest convenience to provide Asheville Hematology with a no review letter stating that the relocation of the existing oncology treatment center and physician office, and the acquisition of a linear accelerator, CT scanner and treatment planning equipment, do not require certificate of need review and are not new institutional health services, within the meaning of the CON law.

Very truly yours,

BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh

² As set forth in the explanation of the clinical equipment attached hereto, in no case would the treatment planning hardware and software be essential to the operation of the CT simulator. Therefore, the cost of that equipment may not be fairly attributed to the cost of the CT simulator for determination as to whether the cost of the simulator would render the facility a diagnostic center.

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July 26, 2005



Via Facsimile and Hand Delivery

Lee B. Hoffman, Chief
Certificate of Need Section
Division of Facility Services
701 Barbour Drive
Raleigh, North Carolina 27603

Re: Asheville Hematology and Oncology Associates, P.A./Relocation and Equipment
Acquisition No Review Request

Dear Ms. Hoffman:

You have inquired as to one calculation set forth in my February 1, 2005 letter related to the above matter. Specifically, the first sentence in the Conclusion on page 6 of that letter states as follows:

Based on the above, the combination of the costs related to the acquisition of the linear accelerator (\$743,039), the acquisition of the CT scanner (\$485,170), the acquisition of treatment planning equipment (\$147,758) and the relocation of the oncology treatment center (\$364,301), totals \$1,758,267, well below the \$2,000,000 threshold.

However, according to your calculation, that total amount should be \$1,740,268, not \$1,758,267 as set forth in my letter. Your calculation is correct, as is confirmed in the Cancer Center Cost Breakdown in Exhibit 2 to that letter, the next to last column of which identifies the total oncology treatment center costs as \$1,740,267.¹ The statement in the Conclusion of the above letter apparently was a calculation error on my part.

¹ The \$1.00 difference between the two is due to computer rounding on the Cancer Center Cost Breakdown.

Ms. Hoffman
July 26, 2005
Page 2

In addition, based on our recent understanding of your position that legal fees related to submitting no review requests should not be included in the cost of a project such as this, the actual capital cost of the project should be reduced further. The legal fees of \$3,600 attributed on line 23 of the Cancer Center Cost Breakdown in Exhibit 2 were related solely to preparing and submitting the no review request, as explained in the Notes thereto. Since you have determined that such fees are not applicable to the cost of the project, this would reduce the capital cost of each aspect of the no review request by \$900, the end result being that the total cost of the project will be as follows:

Acquisition of linear accelerator	\$742,139
Acquisition of CT scanner	484,270
Acquisition of treatment planning equipment	146,858
Relocation of oncology treatment center	<u>363,401</u>
TOTAL CAPITAL COST	\$1,736,668

Please feel free to call me if you have any further questions.

Very truly yours,

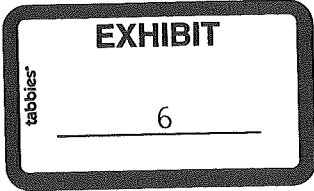
BODE, CALL & STROUPE, L.L.P.



S. Todd Hemphill

STH:sh





North Carolina Department of Health and Human Services
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Lee Hoffman, Section Chief
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August 2, 2005

Todd Hemphill
 Bode, Call, & Stroupe
 3105 Glenwood Avenue
 PO Box 6338
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RE: No Review/ Asheville Hematology and Oncology Associates, P.A./ Acquire a CT simulator
 /Buncombe County

Dear Mr. Hemphill:

In response to your letters of February 1 and March 10, June 16, July 11 and July 26, 2005, on behalf of Asheville Hematology and Oncology Associates, P.A., the above referenced proposal described in your correspondence is not regulated under the Certificate of Need Law and, therefore, does not require a certificate of need. This determination is based on the following representations made in your correspondence regarding the costs of the CT simulator and the activities essential to acquiring and making it operational.

\$485,170.00	Total costs (in letter dated 2/01/05)
\$4,277.62	Costs of ¼ of staff effort (in letter dated 7/11/05)
(\$900.00)	<u>Less ¼ of legal fees for no review prep (in letter dated 7/26/05)</u>
\$488,547.62	Total costs

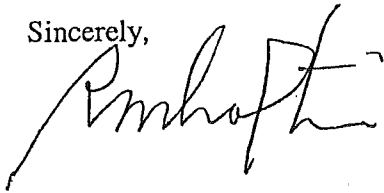
It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



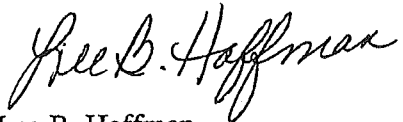
Mr. Hemphill
Page 2
August 2, 2005

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

A handwritten signature in cursive script, appearing to read "R. Loftin".

Ronald Loftin, Project Analyst

A handwritten signature in cursive script, appearing to read "Lee B. Hoffman".

Lee B. Hoffman
Chief Certificate of Need Section

cc: Medical Facilities Planning Section, DFS
Frank Kirschbaum
Brian Moore



North Carolina Department of Health and Human Services
 Division of Facility Services
 Certificate of Need Section

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
 Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffman, Section Chief
 Phone: 919-855-3873
 Fax: 919-733-8139

August 2, 2005

Todd Hemphill
 Bode, Call, & Stroupe
 3105 Glenwood Avenue
 PO Box 6338
 Raleigh, NC 27628-6338

RE: No Review/ Asheville Hematology and Oncology Associates, P.A./ Acquire treatment planning equipment/ Buncombe County

Dear Mr. Hemphill:

In response to your letters of February 1 and March 10, June 16, July 11 and July 26, 2005, on behalf of Asheville Hematology and Oncology Associates, P.A., the above referenced proposal described in your correspondence is not regulated under the Certificate of Need Law and, therefore, does not require a certificate of need. This determination is based on the following representations made in your correspondence regarding the costs of treatment planning equipment and the activities essential to acquiring and making it operational.

\$147,758.00	Total costs (in letter dated 2/01/05)
\$230,000.00	Fair market value of IMPAC record and verify system (in letter dated 6/16/05)
\$4,277.62	Costs of ¼ of staff effort (in letter dated 7/11/05)
<u>(\$900.00)</u>	<u>Less ¼ of legal fees for no review prep (in letter dated 7/26/05)</u>
\$381,135.62	Total costs

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



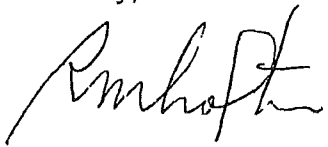
Location: 701 Barbour Drive ■ Dorothea Dix Hospital Campus ■ Raleigh, N.C. 27603
 An Equal Opportunity / Affirmative Action Employer



Mr. Hemphill
Page 2
August 2, 2005

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,



Ronald Loftin, Project Analyst



Lee B. Hoffman
Chief Certificate of Need Section

cc: Medical Facilities Planning Section, DFS
Frank Kirschbaum
Brian Moore



**North Carolina Department of Health and Human Services
Division of Facility Services
Certificate of Need Section**

2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
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Lee Hoffman, Section Chief
Phone: 919-855-3873
Fax: 919-733-8139

August 2, 2005

Todd Hemphill
Bode, Call, & Stroupe
3105 Glenwood Avenue
PO Box 6338
Raleigh, NC 27628-6338

RE: No Review/ Asheville Hematology and Oncology Associates, P.A./ Acquire a linear accelerator/ Buncombe County

Dear Mr. Hemphill:

In response to your letters of February 1 and March 10, June 16, July 11 and July 26, 2005, on behalf of Asheville Hematology and Oncology Associates, P.A, the above referenced proposal described in your correspondence is not regulated under the Certificate of Need Law and, therefore, does not require a certificate of need. This determination is based on the following representations made in your correspondence regarding the costs of the linear accelerator equipment and activities essential to acquiring and making it operational.

\$743,039.00	Costs of linear accelerator equipment
\$4,277.62	Costs for ¼ of staff effort (in letter dated 7/11/05)
<u>(\$900.00)</u>	<u>Less ¼ of legal fees for no review prep (in letter dated 7/26/05)</u>
\$746,416.62	Total costs

It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



Mr. Hemphill
Page 2
August 2, 2005

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,



Ronald Loftin, Project Analyst



Lee B. Hoffman
Chief Certificate of Need Section

cc: Medical Facilities Planning Section, DFS
Frank Kirschbaum
Brian Moore



North Carolina Department of Health and Human Services
 Division of Facility Services
 Certificate of Need Section
 2704 Mail Service Center ■ Raleigh, North Carolina 27699-2704

Michael F. Easley, Governor
 Carmen Hooker Odom, Secretary

<http://facility-services.state.nc.us>

Lee Hoffinan, Section Chief
 Phone: 919-855-3873
 Fax: 919-733-8139

August 2, 2005

Todd Hemphill
 Bode, Call, & Stroupe
 3105 Glenwood Avenue
 PO Box 6338
 Raleigh, NC 27628-6338

RE: No Review/ Asheville Hematology and Oncology Associates, P.A./ Relocate existing oncology treatment center and acquire radiation oncology treatment equipment/Buncombe County

Dear Mr. Hemphill:

In response to your letters of February 1 and March 10, June 16, July 11 and July 26, 2005, on behalf of Asheville Hematology and Oncology Associates, P.A., the above referenced proposal described in your correspondence is not regulated under the Certificate of Need Law and, therefore, does not require a certificate of need. This determination is based on the following representations made in your correspondence regarding the total capital expenditure for the project.

\$381,135.62	Costs of treatment planning equipment
\$488,547.62	Costs of CT simulator equipment
\$746,416.62	Costs of linear accelerator equipment
\$364,301.00	Cost of construction/relocation (in letter dated 2/01/05)
\$1,500.00	Cost of view boxes (in letter dated 6/16/05)
\$4,277.62	Costs for ¼ of staff effort (in letter dated 7/11/05)
<u>(\$900.00)</u>	<u>Less ¼ of legal fees for no review prep (in letter dated 7/26/05)</u>
\$1,985,278.49	Total capital expenditure

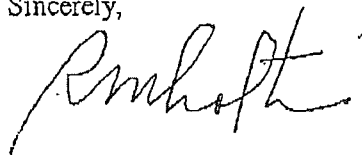
It should be noted that this determination is binding only for the facts represented by you. Consequently, if changes are made in the project or in the facts provided in the correspondence referenced above, a new determination as to whether a certificate of need is required would need to be made by the Certificate of Need Section. Changes in a project include, but are not limited to: (1) increases in the capital cost; (2) acquisition of medical equipment not included in original cost estimate; (3) modifications in the design of the project; (4) change in location; and (5) any increase in the number of square feet to be constructed.



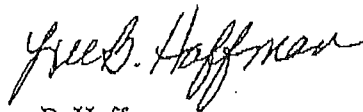
Mr. Hemphill
Page 2
August 2, 2005

Please contact this office if you have any questions. Also, in all future correspondence you should reference the Facility I.D.# (FID) if the facility is licensed.

Sincerely,

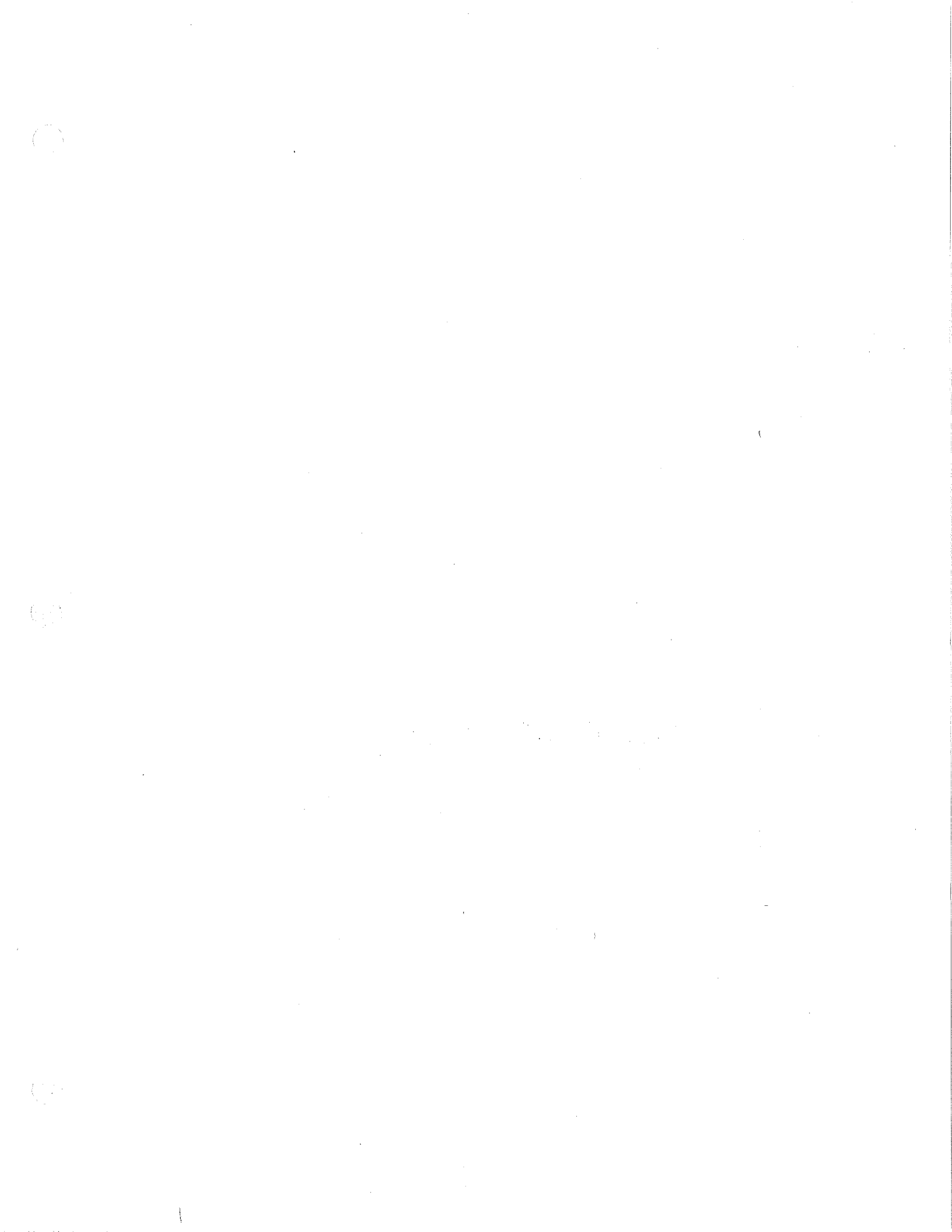


Ronald Loftin, Project Analyst



Lee B. Hoffman
Chief Certificate of Need Section

cc: Medical Facilities Planning Section, DFS
Frank Kirschbaum
Brian Moore





MISSION HOSPITALS, INC., Petitioner, and NORTH CAROLINA RADIATION
THERAPY MANAGEMENT SERVICES, INC., d/b/a 21ST CENTURY
ONCOLOGY, Petitioner-Intervenor, v. NORTH CAROLINA DEPARTMENT OF
HEALTH AND HUMAN SERVICES, DIVISION OF HEALTH SERVICE
REGULATION (FORMERLY DIVISION OF FACILITY SERVICES),
CERTIFICATE OF NEED SECTION, Respondent, and ASHEVILLE
HEMATOLOGY AND ONCOLOGY ASSOCIATES, P.A., Respondent-Intervenor.

NO. COA08-1478

COURT OF APPEALS OF NORTH CAROLINA

696 S.E.2d 163; 2010 N.C. App. LEXIS 1169

June 8, 2009, Heard in the Court of Appeals

July 6, 2010, Filed

PRIOR HISTORY: [**1]

North Carolina Department of Health and Human
Services. No. 05 DHR 1369.

*Mission Hosps., Inc. v. N.C. HHS, 2010 N.C. App. LEXIS
1486 (N.C. Ct. App., June 21, 2010)*

DISPOSITION: AFFIRMED.

COUNSEL: Smith Moore Leatherwood LLP, by
Maureen Demarest Murray and Allyson Jones Labban,
for Petitioner.

Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan,
L.L.P., by Susan H. Hargrove, Sean A. Timmons, and
Courtney H. Mischen, for Petitioner-Intervenor.

Attorney General Roy Cooper, by Assistant Attorney
General June S. Ferrell, for Respondent.

Bode, Call & Stroupe, L.L.P., by Robert V. Bode, S.
Todd Hemphill, Diana Evans Ricketts, and Matthew A.
Fisher, for Respondent-Intervenor.

JUDGES: STEPHENS, Judge. Chief Judge MARTIN
and Judge HUNTER, JR. concur.

OPINION BY: STEPHENS

OPINION

[*166] Appeal by Petitioners from the final agency
decision signed 30 May 2008 by Jeff Horton, Acting
Director for the North Carolina Department of Health and
Human Services, Division of Health Service Regulation.
Heard in the Court of Appeals 8 June 2009.

STEPHENS, Judge.

The present matter was before this Court on a prior
appeal from a Final Agency Decision ("the first FAD")
entered 7 August 2006 by the North Carolina Department
of Health and Human Services ("DHHS" or "the
Agency"). The pertinent factual background of this
matter up to the time of that appeal is set out [**2] in our
opinion in *Mission Hosps., Inc. v. N.C. HHS, 189 N.C.
App. 263, 658 S.E.2d 277 (2008)* ("*Mission I*").¹
However, to aid understanding of the current appeal, we
find it useful to set forth the factual background and
procedural history which brought this matter to our
Court.

¹ Since the entry of our Court's decision in
Mission I, the name of Respondent North Carolina

Department of Health and Human Services, Division of Facility Services, Certificate of Need Section has been changed to "North Carolina Department of Health and Human Services, Division of Health Service Regulation, Certificate of Need Section."

relocation of their oncology treatment center. AHO sought a ruling that its proposals "do not require certificate of need review and are not new institutional health services, within the meaning of the CON law."

Factual Background and Procedural History

On 1 February 2005, Asheville Hematology ("AHO" or appellant), an oncology treatment center, sought a "no-review" determination from the Certificate of Need ("CON") Section of the North Carolina Department of Health and Human Services, Division of Facility Services ("Agency"), for a proposed relocation of its offices and acquisition of medical equipment that would allow AHO to provide radiation therapy. AHO presented four proposals: acquisition of a linear accelerator ("LINAC"), acquisition of a CT scanner, [**3] acquisition of treatment planning equipment, and

In determining the allocable costs for the CT scanner and LINAC projects, AHO applied upfitting costs to accommodate the CT scanner and LINAC and did not allocate general office construction costs, which were instead attributed to the base costs of the developer. AHO clearly specified in its letter which costs were attributed to each project and which costs were attributed to the developer's base costs. [*167] The submitted costs for the four projects, and associated thresholds against which AHO analyzed each of the proposals as a new institutional health service under the statute, were as follows:

Project	AHO's Cost Projection	Statutory Threshold for "No Review"
CT Scanner	\$ 488,547	\$ 500,000 ²
LINAC	\$ 746,416	\$ 750,000 ³
Treatment Planning	\$ 381,135	\$ 750,000 ⁴
Relocation	\$ 1,985,278	\$ 2,000,000 ⁵

On 2 August 2005, the CON Section issued four "no-review" letters, reviewing each proposal separately and confirming that none required a Certificate of Need. [**4] Each letter stated that "this determination is binding only for the facts represented by you." Shortly thereafter, the General Assembly amended *N.C. Gen. Stat. § 131E-176(16)* to require a CON for the acquisition of linear accelerators, regardless of cost, as a new institutional health service. (2005 Sess. Laws ch. 325, § 1). The relevant portion of the amendment became effective on 26 August 2005.

On 1 September 2005, Mission Hospitals, Inc.

("Mission" or "petitioner"), a nonprofit hospital in Asheville, North Carolina, filed a petition for a contested case hearing in the Office of Administrative Hearings ("OAH"), challenging each of the No-Review Determinations. North Carolina Radiation Therapy Management Services, Inc. d/b/a 21st Century Oncology ("21st Century" and, with Mission, "petitioners"), an oncology treatment center in Asheville, North Carolina, intervened in the proceeding, also contesting the No-Review Determinations. AHO intervened in support of the CON Section's No-Review Determinations.

On 26 May 2006, the ALJ entered a 65-page Recommended Decision affirming the No-Review

Determinations. The ALJ agreed with the CON Section that the relocation of the existing oncology [**5] treatment center and the acquisition of equipment as proposed by AHO and addressed in the August 2005 No-Review determinations did not require Certificates of Need. The ALJ recommended that no CON was necessary because neither the relocation nor the acquisition projects "constitute[d] a 'new institutional health service' as defined by *N.C. Gen. Stat. § 131E-176* at the time that [AHO] acquired vested rights to develop these services."

Mission I, 189 N.C. App. at 265-67, 658 S.E.2d at 278-79.

2 See *N.C. Gen. Stat. § 131E-176(7a)* (2003) (governing diagnostic centers).

3 See *N.C. Gen. Stat. § 131E-176(14f)* (2003) (governing acquisition of major medical equipment).

4 *Id.*

5 See *N.C. Gen. Stat. § 131E-176(16)* (2003) (governing capital expenditures).

On 7 August 2006, DHHS entered the first FAD reversing the ALJ's recommended decision. AHO appealed from the first FAD to the Court of Appeals. See *id.* This Court vacated the first FAD upon holding that the Division of Facility Services of DHHS erred by engaging in *ex parte* communications with one party without notice to the other parties or affording an opportunity to all parties to be heard, and that these *ex parte* communications were prejudicial. *Id. at 276, 658 S.E.2d at 285.*

On [**6] remand from this Court, Jeff Horton, Acting Director of the Division of Health Service Regulation of DHHS, entered a second FAD ("FAD") on 30 May 2008. In its FAD, DHHS adopted Administrative Law Judge ("ALJ") Beecher R. Gray's Recommended Decision that AHO's acquisition of a LINAC and a CT scanner and expansion of the oncology treatment center did not require a CON. From the FAD adopting the recommendations of the ALJ, Petitioners appeal.

Standard of Review

Pursuant to *N.C. Gen. Stat. § 150B-34(c)*,

in cases arising under *Article 9 of Chapter 131E of the General Statutes*, the

administrative law judge shall make a recommended decision or order that contains findings of fact and conclusions of law. A final decision shall be made by the agency in writing after review of the official record as defined in *G.S. 150B-37(a)* and shall [**168] include findings of fact and conclusions of law. The final agency decision shall recite and address all of the facts set forth in the recommended decision. For each finding of fact in the recommended decision not adopted by the agency, the agency shall state the specific reason, based on the evidence, for not adopting the findings of fact and the agency's findings [**7] shall be supported by substantial evidence admissible under *G.S. 150B-29(a), 150B-30, or 150B-31*. The provisions of *G.S. 150B-36(b), (b1), (b2), (b3), and (d)*, and *G.S. 150B-51* do not apply to cases decided under this subsection.

N.C. Gen. Stat. § 150B-34(c) (2007).

It is well settled that in cases appealed from administrative tribunals, "[q]uestions of law receive *de novo* review," whereas fact-intensive issues "such as sufficiency of the evidence to support [an agency's] decision are reviewed under the whole-record test." *In re Greens of Pine Glen Ltd. Part.*, 356 N.C. 642, 647, 576 S.E.2d 316, 319 (2003). Thus, where the gravamen of an assigned error is that the agency violated subsections *150B-51(b)(1), (2), (3), or (4)* of the APA, a court engages in *de novo* review. Where the substance of the alleged error implicates subsection *150B-51(b)(5)* or *(6)*, on the other hand, the reviewing court applies the "whole record test."

N.C. Dep't of Env't & Natural Res. v. Carroll, 358 N.C. 649, 659, 599 S.E.2d 888, 894-95 (2004) (internal citations omitted). Under whole record review, the Agency's decision should be reversed only if it is not supported by substantial evidence. *Total Renal Care of N.C. v. N.C. Dep't of Health & Human Servs.*, 171 N.C. App. 734, 739, 615 S.E.2d 81, 84 (2005).

North [**8] Carolina law gives great weight to the Agency's interpretation of a law it administers. *Frye Reg'l Med. Ctr. v. Hunt*, 350 N.C. 39, 45, 510 S.E.2d 159, 163 (1999); see also *Carpenter v. N.C. Dep't of Human Res.*, 107 N.C. App. 278, 279, 419 S.E.2d 582, 584 (1992) (When a court reviews an agency's interpretation of a statute it administers, so long as the agency's interpretation is reasonable and based on a permissible construction of the statute, the court should defer to the agency's interpretation of the statute.); *High Rock Lake Ass'n. v. N.C. Env'tl. Mgmt. Comm'n.*, 51 N.C. App. 275, 279, 276 S.E.2d 472, 475 (1981) (The interpretation of a statute given by the agency charged with carrying it out is entitled to great weight.).

Discussion

I. Amendment to the CON Law

A CON is "a written order which affords the person so designated as the legal proponent of the proposed project the opportunity to proceed with the development of such project." *N.C. Gen. Stat. § 131E-176(3)* (2007). The CON Law, *inter alia*, regulates the acquisition of certain types of equipment. See *Total Renal Care v. Dep't of Health & Human Servs.*, 195 N.C. App. 378, 673 S.E.2d 137, 139-40 (2009) (setting forth the history [**9] and purpose of the CON Law and the procedure involved in obtaining a CON in North Carolina).

AHO submitted a request for a CON determination to the Agency on 1 February 2005. This submission was made in good faith reliance on the CON Law then in existence, *N.C. Gen. Stat. § 131E-175, et. seq.* (2003) (the "prior CON Law"). The CON Law was amended effective 26 August 2005 ("the amended CON Law"), more than six months after AHO's initial submission to the Agency. The amended CON Law changed certain definitions regarding oncology treatment centers and the acquisition and operation of new LINACs. As a result of the amendment, the statutory definition for oncology treatment center was stricken from the text of *N.C. Gen. Stat. § 131E-176(18a)*, and a new definition was added to section 131E-176 defining LINACs.

Petitioners argue that the amended CON Law applies to AHO's acquisition of medical equipment and expansion of its oncology center. Specifically, Petitioners argue that AHO did not have a vested right in the prior CON Law and that AHO acquired the LINAC and CT scanner for purposes of the CON Law after the

amendment became effective. [**169] We are not persuaded by Petitioners' contentions, as [**10] addressed below.

A. Building Lease

On 6 June 2005, AOR Management, as managing agent for AHO, entered into a lease with CC Asheville MOB for the building to which AHO would relocate. AOR Management and CC Asheville MOB modified this lease by amendment twice after the CON Law was amended on 26 August 2005. In its FAD, the Agency found that "the only reasonable reading of the Lease and its subsequent amendments is to view all three writings as one contract memorialized by multiple writings, as contemplated by the Statute of Frauds in North Carolina." Furthermore, the Agency found that "for the purposes of determining the vesting of rights in the Lease of the Building, as set forth above, [AHO] had vested rights in such Lease as of June 6, 200[5]."

A vested right is a common law right that is based upon the constitutional right prohibiting Congress or the State from enacting laws which would impair a party's right to contract. *U.S. Const. amends. V, XIV; N.C. Const. Art. 1, § 19; see Lester Bros., Inc. v. Pope Realty & Ins. Co.*, 250 N.C. 565, 567-68, 109 S.E.2d 263, 265-66 (1959) (Plaintiff had a vested right in the individual liability of defendant, a stockholder of a corporation, stemming [**11] from purchases made from the corporation in 1955, when a 1957 amendment to the law would have relieved defendant of individual liability.). The common law of North Carolina has addressed the issue of vested rights within the context of amendments to statutory law impacting government-issued permits. See generally *Booker v. Duke Med. Ctr.*, 297 N.C. 458, 256 S.E.2d 189 (1979); *Lester Bros.*, 250 N.C. 565, 109 S.E.2d 263. "The proper question for consideration is whether the act as applied will interfere with rights which had vested or liabilities which had accrued at the time it took effect." *Booker*, 297 N.C. at 467, 256 S.E.2d at 195. Furthermore, the good faith reliance of the concerned parties upon the then-existing state of the law is a consideration in determining whether such rights have vested. See *Michael Weinman Assocs. Gen. P'ship v. Town of Huntersville*, 147 N.C. App. 231, 234, 555 S.E.2d 342, 345 (2001) ("[W]here property owners have reasonably made a substantial expenditure of money, time, labor or energy in a good faith reliance of a government approved land-use, they have a vested

right.").

A lease of real estate is the type of contract which creates a vested right. *Carolina Mineral Co. v. Young*, 220 N.C. 287, 290-91, 17 S.E.2d 119, 121-22 (1941) [**12] (right to partition land may be lost or suspended where contractual obligations between tenants are "manifestly inconsistent with partition, especially by sale of the land, and where such a sale would destroy a property right growing out of the lease and guaranteed by it"). Furthermore, the terms of leases "are interpreted according to general principles of contract law." *Wal-Mart Stores, Inc. v. Ingles Markets, Inc.*, 158 N.C. App. 414, 418, 581 S.E.2d 111, 115 (2003). Under contract law, a modification to a lease does not necessarily create a new contract, and rather, the intention of the parties governs. *Id.* at 419, 581 S.E.2d at 115 ("[T]he heart of a contract is the intention of the parties as determined from its language, purposes, and subject matter and the situation of the parties at the time of execution." (internal citation and quotation marks omitted)).

In accordance with our case law, we agree with the Agency's interpretation of AOR Management's lease and conclude that the parties' lease created a vested right in applying the prior CON Law. Accordingly, we analyze the additional issues regarding AHO's building lease under the prior CON Law. The Agency also found that AHO [**13] had a vested right in the purchase contracts for the LINAC and CT scanner. We address the applicability of the appropriate CON Law to these purchase contracts below.

B. Acquisition of Equipment

An acquisition of equipment can occur "by donation, lease, transfer or comparable arrangement[.]" *N.C. Gen. Stat. § 131E-178(b)* (2003). The prior CON Law tied its requirement of a CON for the acquisition of a LINAC or CT scanner to the total cost of the equipment. *N.C. Gen. Stat. § 131E-176(7a)* and *(14f)* (2003). The amended CON [**170] Law, however, requires a CON prior to acquiring a LINAC or CT scanner, regardless of cost. *N.C. Gen. Stat. § 131E-176(16)(f1)(5a)*, and *f1.9*. (2007). The amended CON Law requires a CON prior to making an acquisition of a "new institutional health service" by donation, lease or transfer, or comparable arrangement "if the acquisition would have been a new institutional health service if it had been made by purchase." *N.C. Gen. Stat. § 131E-178(b)* (2007). The definition of "[n]ew

institutional health services" includes "[t]he acquisition by purchase, donation, lease, transfer, or comparable arrangement of . . . [a] [l]inear accelerator[, or a] [s]imulator [by or on behalf of any [**14] person.]" *N.C. Gen. Stat. § 131E-176(16)(f1)(5a)* and *f1.9*.

In its FAD, the Agency made the following pertinent findings of fact:

241. Pursuant to the Management Agreement between AOR Management and Asheville Hematology, US Oncology, through its subsidiary AOR Management, will own the equipment located at Asheville Hematology's relocated oncology treatment center. . . .

. . . .

243. *Whether the equipment is owned by Asheville Hematology or its manager would not impact the CON Section's Determination. Whether a provider acquires medical equipment for purposes of the CON Law by purchase, lease, or other comparable arrangement, the CON Section's treatment of that acquisition is the same under the CON law. Such a comparable arrangement could be through a management agreement. . . . Through its Management Agreement with US Oncology, Asheville Hematology will acquire the equipment to be located in the facility.*

. . . .

248. On June 3, 2005, US Oncology issued a purchase order to Varian for the linear accelerator described in Quotation No. EHD20050511-002. . . .

249. Once US Oncology has issued a purchase order, that binds it to purchase the equipment described in the purchase order. . . .

. . . .

261. [**15] On June 8, 2005, US Oncology issued a purchase order to GE

for the CT scanner

(emphasis added).

Thus, DHHS concluded that AHO acquired the LINAC and CT scanner on 3 June and 8 June 2005, respectively, when the purchase agreements were issued. The Agency further concluded that AHO had vested rights in this equipment as of the date each piece of equipment was acquired.

Our Court's opinion in *Koltis v. N.C. Dep't of Human Res.*, 125 N.C. App. 268, 480 S.E.2d 702 (1997), defined the scope of inquiry with regard to a determination as to whether binding contracts predating a change in the laws of this State continue to be vested. In *Koltis*, the petitioners

proposed to develop and operate a new oncology treatment center in Pitt County, North Carolina. To that end, petitioners notified the North Carolina Department of Human Resources, Division of Facility Services, Certificate of Need Section (DHR) of their ongoing efforts to develop the center and requested DHR's confirmation that the project was exempt from obtaining the certificate of need required for a "new institutional health service" under *N.C. Gen. Stat. § 131E-178*. DHR responded that no certificate of need was required since the [**16] project did not meet the current statutory definition of a "new institutional health service" under *N.C. Gen. Stat. § 131E-176(16)* but warned that pending legislation would significantly change that definition and if enacted, the project would have to be reevaluated in light of the statutory amendment.

Id. at 269, 480 S.E.2d at 703. Section 131E-176 was amended effective 18 March 1993 "so that an oncology treatment center fell within the definition of a 'new institutional health service' requiring a certificate of need under *N.C.G.S. § 131E-178*." *Id.* at 270, 480 S.E.2d at 703. The General Assembly included a "grandfather" provision, however, "which excepted from application of the amended statute 'any person . . . [or] corporation . . . who has lawfully entered into a binding legal contract to

develop and offer any service that was not a new institutional [**17] health service requiring a certificate of need prior to the ratification of this act.'" *Id.* (quoting 1993 N.C. Sess. Laws ch. 7, sec. 12.). On appeal, our Court held that a mere binding contract for "consulting services related to development of the proposed oncology treatment center" which was entered into prior to the amendment to [**17] the CON Law was sufficient to create vested rights on the part of the petitioners. *Id.* at 272, 480 S.E.2d at 705.

In the present case, the Agency found that AHO's purchase contracts for the LINAC and the CT scanner met the definition set forth in *Koltis* of valid, binding contracts, and thus, these contracts gave AHO vested rights in the equipment as of June 2005 under the prior CON Law. Petitioners argue, however, that AHO acquired the equipment after the amended CON Law went into effect, and thus, that AHO did not have any vested rights in the prior CON Law. Petitioners contend that the *purchase* of equipment by US Oncology and the *transfer* of that equipment to AHO were two separate events. Thus, Petitioners argue that although US Oncology acquired the LINAC and CT scanner in June 2005, AHO acquired the equipment when it was transferred to AHO for installation and use at AHO's oncology treatment center after 26 August 2005.

In support of their position, Petitioners argue further that the FAD in the present case contradicts the Agency's decision in 2006 in which DHHS concluded that an acquisition of a LINAC at Thomasville Medical Center ("Thomasville") occurred after the effective date [**18] of the CON Law amendment. In that case, although Forsyth Medical Center ("Forsyth") purchased a LINAC with the intended purpose of installing and using the LINAC at Thomasville, DHHS concluded that Thomasville did not acquire the LINAC until it was actually installed. Thus, although Forsyth purchased the LINAC before the amendment went into effect, DHHS concluded that the amended CON Law applied to Thomasville since the LINAC was installed at Thomasville after the new law went into effect.

In a letter titled "Review Determination & Notice to Cease and Desist" from DHHS to Thomasville, DHHS stated that

[t]he Certificate of Need Section received a December 19, 2005 letter from

Forsyth Medical Center . . . stating that Forsyth Medical Center had purchased a linear accelerator which it intends to install at Thomasville Medical Center. However, the proposal is a new institutional health service within the meaning of N.C. Gen. Stat. § 131E-176(16)f1.5a because it results in the acquisition of a linear accelerator by Thomasville Medical Center by donation, lease, transfer or comparable arrangement.

The record before us does not reveal any relationship between Forsyth and Thomasville beyond [**19] Forsyth's intent to donate a LINAC to Thomasville, nor does the record include any written agreement between the two.

We conclude that Petitioners' reliance on the 2006 Agency decision is misplaced. Unlike Thomasville and Forsyth, AHO and US Oncology share a symbiotic relationship in which US Oncology serves as AHO's "Business Manager." Under the "Management Services Agreement" ("MSA"), US Oncology "provide[s] all Management Services as are necessary and appropriate for the day-to-day administration of the business aspects of AHO's operations[.]" US Oncology's responsibilities as AHO's business manager include: (1) ordering and purchasing medical supplies for AHO; (2) repairing and maintaining AHO's office; and (3) exercising special power of attorney for various purposes including billing AHO's patients. US Oncology purchased the LINAC and CT Scanner on behalf of AHO. Unlike Thomasville's relationship with Forsyth, AHO and US Oncology enjoyed a reciprocal relationship that extended far beyond the donation of a LINAC.

Thus, we conclude that AHO acquired the LINAC and CT scanner by a "comparable arrangement" (*i.e.*, its management agreement with US Oncology) when US Oncology acquired the [**20] LINAC and CT scanner, on 3 June and 8 June 2005, respectively. Accordingly, AHO had vested rights in the equipment as of June 2005 under the prior CON [**172] Law. Furthermore, the Agency rendered its no-review decision on 2 August 2005 determining that AHO's project did not require a CON, prior to the 26 August 2005 effective date of the amendment to the CON Law. Accordingly, we hold that the prior CON Law applies to the determination of whether AHO's project requires a CON.

II. AHO's Acquisition of the LINAC

The Agency found the costs "essential to acquiring and making operational" the LINAC to total \$ 746,416.62. *N.C. Gen. Stat. § 131E-176(14f)* (2003). Because the total cost of the LINAC was found to be less than the \$ 750,000 statutory threshold, the Agency determined that AHO's acquisition of the LINAC did not require a CON. Petitioners argue that the Agency erroneously excluded the record and verify system and the construction costs from this total and that the inclusion of either of these omitted costs would have caused the cost of the LINAC to exceed the statutory threshold and require a CON. We are not persuaded by Petitioners' contention.

A. Record and Verify System

The record and verify [**21] system's primary role is to assure that the patient is treated within the proper parameters as described in the treatment plan. The Agency describes the record and verify system as a single system consisting of a data processing computer and software that processes raw data, including numerical values generated from the views of a tumor and tissues taken by the CT simulator and the data making up the different numerical parameters of the treatment plan, verifying dosage, rate and time of delivery, and creating a record in the computer memory of what transpired during a patient's treatment.

N.C. Gen. Stat. § 131E-178 requires that a CON be obtained before any person acquires "a new institutional health service[.]" *N.C. Gen. Stat. § 131E-178* (2003). An "acquisition by purchase, donation, lease, transfer, or comparable arrangement . . . of major medical equipment" constitutes a "new institutional health service[.]" *N.C. Gen. Stat. § 131E-176(16)p.* (2003).

"Major medical equipment" means 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). [**22] 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.

N.C. Gen. Stat. § 131E-176(14f) (2003) (now subsection (14o), effective 26 August 2005) (emphasis added).

In its brief on appeal, the Agency contends that in applying the statutory phrase, "activities essential to acquiring and making operational the major medical equipment[.]" the Agency applied the customary meaning of "essential" which is "those items which are indispensable, the absence of which renders the equipment useless." N.C. Admin. Code tit. 10A, r. 14C.3102(1) (January 1994). This definition tracks the ordinary meaning of the word, "essential," which is customarily defined to mean "necessary," "indispensable," "inherent," and constituting the "intrinsic character" of a thing. **[**23]** *Webster's Third New International Dictionary 777* (2002).

The Agency concluded that the record and verify system was not "essential to acquiring and making operational" the LINAC, and thus the costs associated with the record and verify system were excluded from the total cost of the LINAC. *See N.C. Gen. Stat. § 131E-176(14f)*. The Agency instead allocated the costs of the record and verify system to the treatment planning equipment.

Petitioners argue that the record and verify system is not separate from the LINAC, and that "[l]ike four-wheel drive in a vehicle, [the record and verify system] has no independent purpose or function, and record and verify services cannot be separated or occur **[*173]** apart from the delivery of radiation by the LINAC." Petitioners contend that the following features of the record and verify system make it essential to the operation of the LINAC: (1) where the parameters of a patient's radiation plan differ from the parameters set on the LINAC, the record and verify system will not allow the LINAC to operate unless manually overridden or disengaged by the radiation therapist; (2) the record and verify system is physically connected or hard-wired to the LINAC; (3) **[**24]** the record and verify system communicates with the LINAC and not with the treatment planning system;

and (4) and the only use for a record and verify system is for use with a LINAC in providing radiation therapy.

Petitioners' argument is inconsistent with this Court's interpretation of the CON Law, however. "[T]he overriding legislative intent behind the CON process [is the] regulation of major capital expenditures which may adversely impact the cost of health care services to the patient." *Cape Fear Mem. Hosp. v. N.C. Dep't of Human Res.*, 121 N.C. App. 492, 494, 466 S.E.2d 299, 301 (1996). In *Cape Fear*, our Court reversed the Agency's determination that Cape Fear Memorial Hospital ("Cape Fear") was required to obtain a CON prior to purchasing an image intensifier and cine camera in an effort to upgrade and expand the capabilities of its existing Angiostar cardiac catheterization equipment ("Angiostar"). *Id.* at 492-93, 466 S.E.2d at 300. This Court held that the Agency's decision would have the effect of allowing micro-management over relatively minor capital expenditures, ⁶ and that "the legislature clearly did not intend to impose unreasonable limitations on maintaining . . . or expanding **[**25]** . . . presently offered health services." *Id.* at 494, 466 S.E.2d at 301 (citing *N.C. Gen. Stat. § 131E-176(14f)* (1994) (CON not required for purchase of unit or system to provide new health service which costs less than \$ 750,000)). Accordingly, we construed *N.C. Gen. Stat. § 131E-175, et. seq.*, as a whole to mean "that the legislature intended 'cardiac catheterization equipment' to include only the actual unit capable of performing cardiac catheterization procedures, not the component parts used to maintain, upgrade, or expand a unit." *Id.*

6 The cost of acquiring the image intensifier and cine camera was found to be \$ 232,510. *Id.* at 495, 466 S.E.2d at 301. In the present case, the fair market value of the record and verify system was found to be \$ 230,000.

Although the present case involves the purchase of a new LINAC and not an existing piece of equipment, our holding in *Cape Fear* is nevertheless instructive to our decision in the case *sub judice*. The Agency's determination that *N.C. Gen. Stat. § 131E-176(14f)* was intended to include only the LINAC and not the component parts used to maintain, upgrade, or expand the unit is consistent with our interpretation in *Cape Fear*. In determining **[**26]** that the record and verify system was a separate unit and not an essential part of the LINAC, the Agency made the following pertinent findings of fact:

34. . . . The Agency has interpreted [N.C. Gen. Stat. § 131E-176(14f)] to mean that if an equipment component is not required for the operation of the proposed item of major medical equipment and it is operated separately from such equipment, then the two items of equipment are not a single system of components, and the equipment component is not essential to making operational the major medical equipment. . . .

....

41. In correspondence to the Agency prior to the Determination, Asheville Hematology described the record and verify system as follows:

When treating patients with radiation on a linear accelerator, the use of a record and verify system serves as an optional component of a quality control system for the radiation therapists. The record and verify system provides electronic validation of the daily treatment parameters but is not necessary in administration of radiation therapy. As such, it is an optional part of the treatment planning system, which is a separate piece of medical equipment

....

[*174] 43. Asheville Hematology [**27] also notified the CON Section that it can operate the treatment planning system without this record and verify system. . . .

44. Only 74 of the 94 radiation sites US Oncology manages have chosen to

install a record and verify system. . . .

45. The record and verify system is a separate piece of equipment from and is not attached to the linear accelerator. It is manufactured by a company other than Varian, the manufacturer of Asheville Hematology's proposed linear accelerator. . . .

46. The record and verify system's primary role is to assure that the patient is treated with the proper parameters as described in the treatment plan. . . .

47. The record and verify system does not turn the linear accelerator "on" for the purpose of delivering radiation. Rather, it sets up the linear accelerator so that it is ready to deliver radiation, by ensuring that treatment parameters contained in the treatment plan are accurate. In that regard, the record and verify system is an extension of the treatment planning system, because it manages the data contained in the treatment plan and provides it to the linear accelerator for delivery. . . .

....

51. [Lee Hoffman, Chief of the CON Section,] saw the [**28] record and verify system as a communication link or a bridge between the treatment plan and the delivery of the treatment. As a result, she determined that it was part of the treatment planning [equipment] because it was to assure that the treatment delivered was consistent with the treatment plan. . . .

The Agency's findings are supported by the testimony of AHO witnesses, Mission's expert witnesses, and by the testimony of Lee Hoffman ("Hoffman"), the Chief of the CON Section. Prior to making the no-review determination, Hoffman visited Duke Health Raleigh Hospital's radiation oncology program. Hoffman met with Duke Health Raleigh staff, viewed the LINAC, and reviewed the documentation for their record and verify system. Duke Health Raleigh treated the record and

verify system consistently with the way that AHO had represented to the Agency: that is, as a separate treatment planning system apart from the LINAC.

Accordingly, the Agency's determination that the record and verify system was not "essential to acquiring and making operational" the LINAC is supported by substantial evidence in the record and is consistent with the CON Law. Petitioners' argument regarding the record and verify [**29] system is overruled.

B. Construction Costs

Petitioners also argue that the Agency erroneously excluded two categories of construction costs when calculating the total costs for the LINAC: (1) the "general conditions" costs, and (2) the costs associated with construction of the space to house the mechanical room or the mold room. Timothy Knapp, an architect and witness for 21st Century, testified that general conditions are the general contractor's costs related to the overall construction of a project which are not specifically related to any one particular aspect of the construction project. Bryan Royal ("Royal"), a project manager for one of the contractors involved with the AHO Project and a witness for AHO, testified that general conditions costs include costs such as contractor employee salaries, construction trailer, office supplies, porta-johns, storage trailers, temporary utilities, waste receptacles, and clean-up.

The Agency found that the projected cost for the LINAC was \$ 746,416.62. Royal testified that the general conditions costs attributable to the LINAC vault totaled \$ 23,418.00. Thus, had the Agency included these costs in calculating the cost of the LINAC, the total [**30] would have exceeded the \$ 750,000 statutory threshold and required a CON.

Petitioners' argument is flawed, however, as the general conditions costs attributable to the LINAC vault did not increase the cost of general conditions related to the cost of construction for the medical [*175] office building. In its FAD, the Agency found that "[h]ad the vault not been constructed, total general conditions would have been the same. Consequently, there [were] no additional general condition cost[s] incurred to build the [LINAC] vault." In addition, a new medical office building is not "essential" to acquiring and making operational a LINAC. See *N.C. Gen. Stat. § 131E-176(14f)*. Accordingly, the general conditions costs

of the LINAC vault were properly excluded from the projected cost of the LINAC.

Petitioners also contend that the costs associated with constructing the space to house the mechanical room and mold room were erroneously excluded from the total cost of the LINAC. The Agency classified these costs as "developer's base costs" which Hoffman testified are not included in the cost of health service. The Agency made the following findings of fact with regard to the developer's base costs:

61. Ms. [**31] Hoffman explained her reasoning during the contested case hearing as to why developer's base costs are not included in the cost of the health service. She explained that the development of an office building, including a medical office building, is not a capital expenditure falling within the statutory definition of "new institutional health service" under the CON Law. . . .

62. If the builder is unrelated to the entity which will be providing the health service, and is only leasing space to the health service, then the CON Section only will look at what costs are going to be incurred to make that office building a health service facility. That is consistent with the way exemptions are handled in *G.S. § [131E-184(a)]*, so the CON Section looks at no review requests the same way. . . .

63. If the builder is a party which is related to the provider of the health service, the CON Section considers the builder to be developing the health service facility, and therefore, the entire cost of the facility would be considered. . . .

70. Neither Asheville Hematology nor US Oncology owns the Building or the land on which it is being constructed. Both are owned by CC Asheville MOB. . . .

Based [**32] on the record before us, the Agency's

findings are supported by the evidence and support the Agency's conclusion that the developer's base costs were not attributable to the LINAC. Petitioners' argument is overruled.

III. AHO's Acquisition of the CT Scanner

Next, Petitioners contend the Agency erroneously concluded that AHO's acquisition of the CT scanner was exempt from the CON requirements. We disagree.

Under the CON Law, a CON must be obtained before establishing a diagnostic center, which is defined as

a freestanding facility, program, or provider, including but not limited to, physicians' offices, clinical laboratories, radiology centers, and mobile diagnostic programs, in which the total cost of all the medical diagnostic equipment utilized by the facility which cost ten thousand dollars (\$ 10,000) or more exceeds five hundred thousand dollars (\$ 500,000). In determining whether the medical diagnostic equipment in a diagnostic center costs more than five hundred thousand dollars (\$ 500,000), the costs of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational ****33** the 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.

N.C. Gen. Stat. § 131E-176(7a) (2003).

Because a CT scanner is considered medical diagnostic equipment, the Agency found that

the utilization of any medical diagnostic equipment, including a diagnostic CT scanner, which cost in excess of \$ 500,000, would cause Asheville Hematology to be a diagnostic center, which is a new institutional health service. Because Asheville Hematology is not

currently a diagnostic center, it would not be able to acquire a diagnostic CT scanner without a CON, if the cost to acquire and make operational the CT scanner and the cost of any other medical diagnostic equipment currently utilized or proposed to be utilized at the facility would exceed \$ 500,000. . . .

[*176] The Agency determined the total cost to acquire and make operational the CT scanner to be \$ 488,547.62. Because the total cost was less than \$ 500,000, the Agency concluded that the acquisition of the CT scanner did not require a CON. The Agency made the following findings of fact with regard to the costs associated ****34** with the CT scanner:

310. . . . [T]he final purchase price for the diagnostic CT scanner of \$ 308,500 is reasonable and supported by the preponderance of the evidence.

311. Mr. Royal's and Mr. Kury's ⁷ estimates and allocations of total construction costs related to the CT scanner as presented at the hearing properly included the construction of all space essential to the installation and operation of the CT scanner. Petitioners were given a thorough opportunity to cross examine Mr. Royal and Mr. Kury on the bases for those estimates, and the witnesses were able to demonstrate that all of the essential construction costs were included and supported by back-up documentation.

312. Further, . . . equipment used for simulation which is not essential to the performance of diagnostic CT scans should not be included in the \$ 500,000 diagnostic center cost threshold, because such equipment is not medical diagnostic equipment within the meaning of the CON Law.

313. ****35** Asheville Hematology's estimate of equipment and other costs essential to the operation of the CT scanner as presented at the hearing

properly identified all such essential equipment, and the cost attributed to that equipment was reasonable.

314. The preponderance of the evidence demonstrates that the actual cost to acquire and make operational the Asheville Hematology diagnostic CT scanner will not exceed \$ 500,000.

7 "Mr. Kury" refers to Mark Kury, Vice President of Centex-Concord, the developer of the AHO project.

The above findings of fact support the Agency's conclusion that AHO's acquisition of the CT scanner did not require a CON. Petitioners, however, argue that several necessary costs were excluded from the Agency's determination, and that had any of these costs been included, the cost of the CT scanner would have exceeded the \$ 500,000 threshold. Among these excluded costs are: (1) the entire cost of CT diagnostic contrast equipment valued at \$ 21,000; (2) presently owned diagnostic equipment totaling \$ 20,598; (3) the cost of constructing the CT room and control room totaling \$ 118,745 or alternatively \$ 104,716; and (4) the portion of the capital lease attributable to the CT [*36] scanner valued at \$ 165,156. We address each of these contested items below.

A. Total Cost of CT Diagnostic Contrast Equipment

Included in the cost of the CT scanner was certain used diagnostic contrast equipment. This equipment was to be transferred from another US Oncology facility to AHO's new facility. The Agency found that

this equipment is fully depreciated and has no market value, because there is not a secondary market where it could be sold. Asheville Hematology's estimate of 40% [of the original cost of the equipment] was a conservative estimate of the equipment's value. In reality, if it could not be relocated to another US Oncology facility, it would be thrown away.

Thus, the Agency allocated \$ 8,400, or 40% of the original price of \$ 21,000, to the CT scanner for this

diagnostic contrast equipment.

Petitioners argue that the entire \$ 21,000 should have been allocated to the CT scanner. This would add \$ 12,600 to the total cost of the CT scanner, bringing the total cost of the CT scanner to \$ 501,147.62, which is in excess of the \$ 500,000 CON threshold.

N.C. Gen. Stat. § 131E-176(7a) provides that "[t]he capital expenditure for the equipment shall be deemed to be the fair market [**37] value of the equipment or the cost of the equipment, whichever is greater." *N.C. Gen. Stat. § 131E-176(7a)*. Petitioners contend that for purposes of the statute, "the cost" of the diagnostic contrast equipment was the cost of the equipment when it was originally purchased, \$ 21,000, which was greater than the fair market value of the equipment, [*177] \$ 8,400. Thus, Petitioners argue that the Agency erroneously excluded \$ 12,600 from its calculation of the total cost of the CT scanner. We are not persuaded by Petitioners' argument.

The diagnostic contrast equipment to be used with the CT scanner was estimated to be three to four years old and had fully depreciated by the time it was acquired by AHO. The equipment was estimated to be worth 40% of the cost of purchasing new equipment, and the Agency found that the equipment had no market value because there was no secondary market in which it could be sold. Thus, "the greater" of the cost or fair market value of the used diagnostic contrast equipment was properly determined to be \$ 8,400, which was properly allocated to the cost of the CT scanner.

B. Presently Owned Diagnostic Equipment

At AHO's existing facility, AHO housed a type of diagnostic [**38] equipment called a "Coulter counter," which AHO purchased in 2003 for \$ 20,598. Petitioners argue that the Agency erroneously excluded this amount from the total cost of the CT scanner. Petitioners, however, have identified no evidence, nor have they argued, that this piece of equipment was essential to acquiring and making operational the CT scanner. Thus, we cannot conclude that the Agency erred in excluding the presently owned diagnostic equipment from the cost of the CT scanner.

C. Construction Costs for the CT Room

The Agency found that "Mr. Royal's and Mr. Kury's

estimates and allocations of total construction costs related to the CT scanner as presented at the hearing properly included the construction of all space essential to the installation and operation of the CT scanner." The Agency further found that "Petitioners were given a thorough opportunity to cross examine Mr. Royal and Mr. Kury on the bases for those estimates, and the witnesses were able to demonstrate that all of the essential construction costs were included and supported by back-up documentation." Petitioners now contend that construction costs for the CT room and control room were erroneously omitted from the [**39] total cost of the CT scanner. Petitioners fail to demonstrate, however, that the Agency's findings were in error, and argue only that "[n]one of these spaces would be necessary except for the CT [scanner]." Petitioners have not shown that either the CT room or the control room was essential to the installation and operation of the CT scanner. Accordingly, the construction costs for these spaces were properly omitted from the determination of the total cost of the CT scanner.

D. Portion of Building Lease Attributable to CT Scanner

Petitioners also argue that a portion of AHO's lease of its new facility should be allocated to the CT scanner. Petitioners' argument is based on their incorrect assumption that AHO's lease was a capital lease. As we discuss *infra*, AHO's building lease is an *operating* lease, not a *capital* lease, which is not subject to CON review. Thus, no part of AHO's lease was attributable to the CT scanner and this was properly excluded.

Based on the foregoing, we conclude that the Agency correctly determined that AHO's acquisition of a CT scanner for its new facility did not require a CON. Petitioners' argument is overruled.

IV. Expansion of Oncology Treatment Center

Petitioners [**40] also argue that the Agency erroneously concluded that AHO's expansion of its existing oncology treatment center was exempt. We disagree.

A. Physician Office Building

AHO was formed in 1982 to engage in the practice of medical oncology. Thus, AHO was in existence as a physician practice specializing in oncology 11 years prior to the 1993 enactment of the CON requirements for new

oncology treatment centers, diagnostic centers, and acquisition of major medical equipment. In 1984, the physician owners of AHO formed a partnership⁸ in order to purchase [**178] real estate in Asheville, North Carolina, construct a building for a medical oncology practice ("the Facility"), and lease the Facility to AHO. In its 1 February 2005 letter, AHO informed the Agency that AHO had entered into a tentative lease agreement with CC Asheville MOB⁹ to relocate the Facility to a new building which was constructed by CC Asheville MOB. CC Asheville MOB incurred all construction costs and would maintain ownership of the new building while AHO leased its space pursuant to an operating lease.

8 The partnership formed by the physician owners of AHO is Paschal, Jackson, Puckett and Davis General Partnership.

9 In AHO's 1 February [**41] 2005 letter to the Agency, the building developer and owner is referred to as "Centex Development Company." In the Agency's FAD, CC Asheville MOB is referred to as the owner of AHO's new facility. CC Asheville MOB is a subsidiary of Centex-Concord, and while it appears that Centex-Concord is affiliated with Centex Development Company, the record does not confirm this relation.

It is undisputed that AHO is an oncology treatment center within the meaning of *N.C. Gen. Stat. § 131E-176(18a)*. The Agency found that because of this, AHO is an existing health service facility. The Agency further found that

[u]nder the law applicable to the CON Section's Determination, an existing oncology treatment center may relocate its oncology treatment center and acquire certain items of medical equipment without obtaining a certificate of need, so long as the cost to acquire and make operational each unit of equipment does not exceed \$ 750,000, and so long as the combination of the costs to acquire and make operational all such equipment and all other costs related to relocating the oncology treatment center, do not exceed \$ 2,000,000.

Thus, the Agency treated AHO's expansion and

relocation of its office [**42] building as a "physician office building" which does not require a CON so long as the total cost of expansion and relocation of said office building does not exceed \$ 2,000,000. See *N.C. Gen. Stat. § 131E-176(16)(b)* and *184(a)(9)* (2003).

Petitioners, however, argue that because AHO was an existing oncology treatment center, AHO's expanded and relocated office building must be treated as a "health service facility," defined by *N.C. Gen. Stat. § 131E-176(9b)*, rather than an unregulated "physician office building." If AHO's new office building was deemed a "health service facility," the entire cost of the land and building for the relocated AHO office would be included as a "capital expenditure" which would count toward the expansion of an oncology treatment center. Thus, no part of AHO's project would be exempt under the "physician office building" exemption. Petitioners' argument is contrary to the CON Law, however. The CON Law provides that an exempt physician office building may include certain non-exempt portions, such as an oncology treatment center, which is the case here.

N.C. Gen. Stat. § 131E-184(a)(9) provides in pertinent part that

the Department shall exempt from certificate [**43] of need review a new institutional health service if it receives prior written notice from the entity proposing the new institutional health service, which notice includes an explanation of why the new institutional health service is required . . . [t]o develop or acquire a physician office building regardless of cost, unless a new institutional health service other than defined in *G.S. 131E-176(16)b*. is offered or developed in the building.

N.C. Gen. Stat. § 131E-184(a)(9) (2003). If another type of "new institutional health service" is developed in the building, *N.C. Gen. Stat. § 131E-184(b)* nonetheless preserves the exemption for the physician office building while allowing regulation of the non-exempt portions.

Those portions of a proposed project which are not proposed for one or more of the purposes under subsection (a) of this section are subject to certificate of need review, if these non-exempt portions of

the project are new institutional health services under *G.S. 131E-176(16)*.

N.C. Gen. Stat. § 131E-184(b) (2003).

The physician office building exemption applies to (1) developing or acquiring a physician office building regardless of cost, and (2) offering or developing "in [**44] the building" a new institutional health service as defined by [**179] *N.C. Gen. Stat. § 131E-176(16)b*. Thus, the following projects in a physician office building are exempt:

[t]he 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. Gen. Stat. § 131E-176(16)(b). (2003).

Reading *N.C. Gen. Stat. §§ 131E-176(16)(b)*., *184(a)(9)*, and *184(b)* together, the CON Law therefore exempts "a capital expenditure . . . to develop or expand a health service or a health service facility, or which relates to the provision of a health service[.]" *N.C. Gen. Stat. § 131E-176(16)(b)*., if it is "in the [physician office] building." *N.C. Gen. Stat. § 131E-184(a)(9)*. [**45] Accordingly, the Agency here considered the equipment which would expand the services of the oncology treatment center -- the LINAC, the CT scanner, and the treatment planning equipment. The Agency found that

[t]he CON Section's "no review" determination for relocation of the existing oncology treatment center, including the acquisition of the radiation oncology treatment equipment, attributed the following activities for purpose of determining the applicability of CON

review:

\$ 381,135.62	Costs of the treatment planning equipment
\$ 488,547.62	Costs of the CT simulator equipment
\$ 746,416.62	Costs of the linear accelerator equipment
\$ 364,301.00	Costs of the construction/relocation (in letter dated 2/01/05)
\$ 1,500.00	Costs of the view boxes (in letter dated 6/16/05)
\$ 4,277.62	Costs for 1/4 of staff effort (in letter dated 7/11/05)
(\$ 900.00)	Less 1/4 of legal fees for no review prep (in letter dated 7/26/05)
\$ 1,985,278.49	Total costs

Thus, the Agency properly focused on whether the costs *essential* to acquiring this equipment and making it operational exceeded the \$ 2,000,000 threshold, and excluded the part of the project that was exempt as a physician office building. The Agency defines "essential" to mean **[**46]** "those items which are indispensable, the absence of which renders the equipment useless." N.C. Admin. Code tit. 10A, r. 14C.3102(1) (January 1994). The Agency's definition of "essential" as applied to major medical equipment has been in effect since 1993 and has not been modified by the General Assembly which suggests agreement with the Agency's interpretation. Further, the Agency's interpretation is consistent with the General Assembly's intention because Agency

micro-management over relatively minor capital expenditures . . . does not effectuate the overriding legislative intent behind the CON process, *i.e.*, regulation of major capital expenditures which may

adversely impact the cost of health care services to the patient. . . . Nevertheless, the legislature clearly did not intend to impose unreasonable limitations on maintaining . . . or expanding . . . presently offered health services.

Cape Fear Mem. Hosp., 121 N.C. App. at 494, 466 S.E.2d at 301. Accordingly, Petitioners' argument is overruled.

B. Building Lease

Petitioners also argue that AHO's lease of the building which was to house AHO's relocated oncology treatment center was a capital lease, and thus it was a capital expenditure **[**47]** which should be counted toward the \$ 2,000,000 threshold pursuant to *N.C. Gen. Stat. § 131E-176(16)(b)*. We disagree.

In its FAD, the Agency explained that under

generally accepted accounting principles ("GAAP"), a building lease may be classified as an operating lease or a capital lease, depending upon certain circumstances. A capital lease is treated differently on a company's books than an operating lease. A capital lease is considered a financing arrangement under GAAP, such that it is an asset in the balance sheet of the lessee, with an off-setting debt in the balance sheet liabilities. [*180] An operating lease, however, would not be shown in the balance sheet. Rather, the expense of an operating lease would be shown in the company's income statement.

On 6 June 2005, AOR Management, a subsidiary of US Oncology and managing agent for AHO, entered into a lease with CC Asheville MOB, for a building and the land on which it was located to be used for its oncology treatment center. On 2 September 2005, AOR Management and CC Asheville MOB entered into a "First Amendment to Lease Agreement[.]" In its FAD, the Agency found that at the time the lease and the first amendment were executed, US Oncology [**48] believed the lease to be an operating lease. However, Kevin Krenzke ("Krenzke"), a certified public accountant and Vice President and Controller of US Oncology, later concluded that under GAAP, the lease and first amendment constituted a capital lease.

On 31 March 2006, AOR Management and CC Asheville MOB entered into a "Second Amendment to Lease Agreement[.]" in which the parties renegotiated the lease in a manner that changed the minimum lease payments. Krenzke applied GAAP, and concluded that the second amendment was an operating lease.

The Agency's findings in the FAD establish that AHO's lease is an operating lease and not a capital lease. Specifically, the Agency made the following pertinent findings:

281. Under FASB 13, a lease would be a capital lease if (a) the lease transfers ownership of the property at the end of the term; (b) the lease contains a bargain purchase option; (c) the lease term is equal to 75% or more of the estimated life of the leased property; or (d) the present value at the beginning of the lease term of the minimum lease payments equals or exceeds 90% of the fair market value of the leased property. . . .

. . . .

283. Centex-Concord, the parent company of CC [**49] Asheville MOB, is a development company engaged in the primary business of constructing, owning, leasing, and selling real estate development properties. As such, it meets the definition of a manufacturer for determining the fair market value of the property. For the same reason, the value defined in an appraisal would be the proper basis for determining whether a lease for property developed by Centex-Concord is a capital lease or an operating lease under the 90% test. . . .

284. An appraisal of the property owned by CC Asheville MOB was conducted by Fred H. Beck and Associates ("Beck") in August 2005. Beck appraised the fair market value of the leased property as \$ 8,500,000. . . .

. . . .

288. At the time the Lease and the First Amendment were executed, it was US Oncology's understanding that the Lease was an operating lease. After the First Amendment was executed, it and the Lease were submitted by US Oncology's capital planning group to Mr. Krenzke in his financial reporting capacity, to confirm whether or not that conclusion was correct. By the time his analysis was completed, he concluded that the Lease and the First Amendment as structured constituted a capital lease. . . .

. . [**50] . .

290. [Because US Oncology prefers all leases to be operating leases,] US Oncology and Centex-Concord renegotiated the Lease so that the minimum lease payments were changed under the Second Amendment. Instead of a 2.5% annual increase in the minimum rental payment, the annual increase would be tied to the Consumer Price Index

("CPI"), with a minimum annual increase of 1% and a maximum annual increase of 4%. . . .

. . . .

296. For purposes of determining whether the Second Amendment is a capital lease, it is appropriate to value the property at \$ 8,500,000, as per the Beck appraisal. The preponderance of the evidence shows that the terms of the Second Amendment would not cause the appraised value in the Beck appraisal to decrease.

297. Further, under the Second Amendment, the present value at the beginning of the lease term of the minimum lease payments [*181] would be calculated under GAAP based upon a 1% annual increase. Using those assumptions, the present value at the beginning of the lease term of the minimum lease payments would be less than 90% of the fair market value of the leased property. . . . *Therefore, the Second Amendment is an operating lease.*

(Emphasis added).

Petitioners argue [**51] that for purposes of the CON Law, AHO incurred the expense of the lease when it first entered into the lease on 6 June 2005. Thus, Petitioners contend that when deciding whether AHO's lease constituted a capital expenditure, the Agency should have looked at the initial lease -- a *capital* lease -- which, by its nature, constituted a capital expenditure. We disagree.

N.C. Gen. Stat. § 131E-176(16)b. requires a CON for a capital expenditure exceeding \$ 2,000,000. The CON Law defines a "capital expenditure" 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. Gen. Stat. § 131E-176(2d) (2003) (emphasis added). Furthermore, the Agency found that a capital lease would not be "an acquisition made by donation, [**52] lease, or comparable arrangement by which a person obtains equipment," *N.C. Gen. Stat. § 131E-176(2d)*, and therefore would not be a capital expenditure under *N.C. Gen. Stat. § 131E-176(2d)*, because it is not a lease of equipment. Thus, even assuming *arguendo* that AHO's lease constituted a capital lease, it would not have been a capital expenditure for purposes of the CON Law. Accordingly, Petitioners' argument is overruled.

C. Staff Costs

Petitioners argue that staff costs which were attributable to the relocation and expansion of AHO's oncology treatment center were erroneously excluded in the CON determination. We disagree.

The Agency considered AHO's staff costs irrespective of the relocation and expansion of its oncology treatment center and determined that AHO did not incur any additional staff costs as a result of its project. The Agency made the following findings of fact:

216. In its July 11, 2005 letter, Asheville Hematology provided documentation of \$ 17,110.49 in internal staff costs as of that date. . . .

. . . .

221. Ultimately, the evidence offered indicated that all actual internal staff costs incurred by Asheville Hematology/US Oncology to date, along with the prospective [**53] staff costs reasonably anticipated to be incurred prior to the treatment of the first patient at the new Asheville Hematology facility, total \$ 30,402.41. . . .

. . . .

227. All the foregoing staff members were salaried employees of Asheville Hematology/US Oncology and that no additional cost was incurred as a result of their efforts in furtherance of the project. Their salaries would have been paid irrespective of the Asheville Hematology Project. . . .

228. Neither *G.S. § 131E-176(7a)* ("diagnostic centers") nor *G.S. § 131E-176(14d)* ("major medical equipment") specifically includes staff costs among the costs which are deemed essential to the operation of that equipment. Only *G.S. § 131E-176(16)(b)* ("New Institutional Health Service" / \$ 2 million total capital expenditure) specifically mentions staff costs in the cost threshold determination.

229. [Lee] Hoffman stated, however, that in her opinion these staff costs were nonetheless attributable to the linear accelerator, the CT scanner, the treatment planning equipment, and total capital costs for the Asheville Hematology Project, despite the fact that no additional cost was incurred [*182] by Asheville Hematology/US Oncology as a result of their [*54] efforts in furtherance of the project. . . .

230. Furthermore, Ms. Hoffman admitted that, in numerous prior no-review determinations, the Agency had not included the cost of internal staff time in furtherance of a project in the total capital costs essential to making a health service operational. . . .

231. In light of the foregoing, there were no staff costs, above and beyond staff costs which would have otherwise been incurred by Asheville Hematology or US Oncology irrespective of the Asheville Hematology Project, and therefore, there were no additional capital costs attributable to the Asheville Hematology Project, for the efforts of salaried staff in furtherance of the Asheville Hematology

Project.

232. Notwithstanding this fact, even if costs related to the efforts of salaried staff in the employ of Asheville Hematology or US Oncology in furtherance of the Asheville Hematology Project are attributable, the allocations of the staff costs associated with the development of the Asheville Hematology Project are reasonable in light of the evidence adduced.

Petitioners contend that the Agency erroneously excluded the \$ 30,402.41 AHO reported in internal staff costs as of 11 July 2005 from [*55] its CON determination. Petitioners do not, however, demonstrate that the Agency's findings were unsupported by substantial evidence or otherwise erroneous, and thus, this argument is overruled.

V. Certified Cost Estimate

Under the CON Law, if a licensed architect or engineer provides a valid cost estimate and certifies that the costs contained in the estimate are "equal to or less than the expenditure minimum for capital expenditure for new institutional health services, such expenditure shall be deemed not to exceed the amount for new institutional health services regardless of the actual amount expended," provided that the following requirements are met: (1) the licensed architect or engineer must certify the costs; (2) the certified cost estimate must be issued in writing at least 60 days before the obligation for the capital expenditure is incurred; and (3) the proponent must notify the Agency in writing within 30 days of any expenditure that exceeds the expenditure minimum. *N.C. Gen. Stat. § 131E-178(d)* (2003).

As part of its 1 February 2005 submission to the Agency, AHO provided an architect's estimate of the expected costs and a series of cost breakdowns for the proposed cancer [*56] center. AHO provided a letter and supporting materials from the licensed architect responsible for the design and management of the project as a certified estimate of the construction costs with the attached cost breakdowns. AHO's architect estimated the costs for the project to be less than the applicable thresholds in the CON Law.

Petitioners argue that AHO's estimate did not qualify as a certified estimate under *section 131E-178(d)*. The Agency did not ultimately decide whether the estimate provided by AHO's architect qualified as a certified cost estimate under this section, because the Agency found that the evidence established that the actual construction costs for the project would not exceed the relevant cost thresholds in the CON Law. Thus, the Agency found that *section 131E-178(d)* was not applicable in this instance. In light of the Agency's finding and based on our holding that the Agency properly determined the AHO project did not require a CON, we need not decide whether AHO's cost estimate constituted a certified cost estimate under *section 131E-178(d)*.¹⁰

10 Nonetheless, it is obvious from the Agency's findings set out above, which are supported by substantial evidence in [**57] the record, that Petitioners' argument lacks merit.

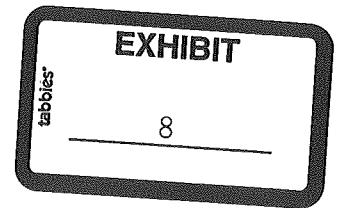
Conclusion

For the foregoing reasons, we affirm the Final Agency Decision adopting the recommended decision of the Administrative Law Judge.

AFFIRMED.

Chief Judge MARTIN and Judge HUNTER, JR.
concur.





North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

August 18, 2011

CERTIFIED MAIL

Bode Call & Stroupe, L.L.P.
S. Todd Hemphill, Esquire
Post Office Box 6338
Raleigh, NC 27628-6338

RE: Declaratory Ruling for Radiation Oncology Centers of the Carolinas, Inc.

Dear Mr. Hemphill:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR
Craig Smith, Chief, Certificate of Need Section
Steven Lewis, Chief, Construction Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
DHSR Medical Facilities Planning Section
Marc Lodge, Special Deputy Attorney General, DOJ



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

**IN RE: REQUEST FOR DECLARATORY)
RULING BY RADIATION ONCOLOGY) DECLARATORY RULING
CENTERS OF THE CAROLINAS, INC.)**

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services (“Department” or “Agency”), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Radiation Oncology Centers of the Carolinas, Inc. (“ROCC”) has requested a declaratory ruling to confirm that the transfer of two CON-approved radiation oncology facilities to two wholly owned subsidiaries (the “Proposed Transaction”) will not constitute a new institutional health service or require a CON. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. S. Todd Hemphill of Bode, Call & Stroupe, L.L.P. has requested this ruling on ROCC’s behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

ROCC directly owns and operates two CON-approved radiation oncology facilities. University Radiation Oncology Center (“UROC”), located at 8310 University Executive Park, Suite 500, Charlotte, NC 28262, was acquired by ROCC in 1997 pursuant to an exemption.

Matthews Radiation Oncology Center (“MROC”), located at 1400 Matthews Township Parkway, Matthews, NC 28105, is a “grandfathered” facility, because it became operational in 1990, prior to the application of the CON law to oncology treatment centers or major medical equipment.

The radiation oncology equipment located at UROC includes a Varian 2100C linear accelerator and a GE Highspeed Advantage CT simulator. The radiation oncology equipment located at MROC includes a Varian 21Ex-d linear accelerator and a GE Brightspeed CT simulator. Acquisition of the linear accelerator and CT simulator equipment at each facility has been previously approved by the agency.

ROCC would like to transfer its interest in UROC and MROC to two wholly owned subsidiaries of ROCC.

ANALYSIS

The CON law provides that no person shall offer or develop a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new institutional health services includes “the acquisition by purchase, donation, lease, transfer or comparable arrangement” of a linear accelerator or simulator “by or on behalf of any person,” N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and “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,” N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like ROCC which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioner is consistent with the Department’s prior rulings that

have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

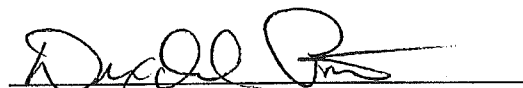
The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the CON and have been used to furnish oncology treatments to patients.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new, or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioner does not require a certificate of need in order to proceed with the Proposed Transaction.

This the 18th day of August, 2011.



Drexal Pratt, Director
Division of Health Service Regulation
N.C. Department of Health and Human Services

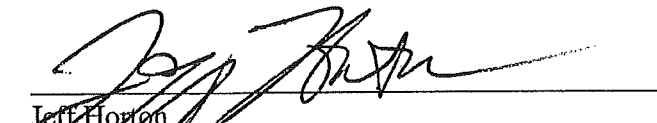
CERTIFICATE OF SERVICE

I certify that a copy of the foregoing Declaratory Ruling has been served upon the nonagency party by facsimile and certified mail, return receipt requested, by depositing the copy in an official depository of the United States Postal Service in a first-class, postage pre-paid envelope addressed as follows:

CERTIFIED MAIL

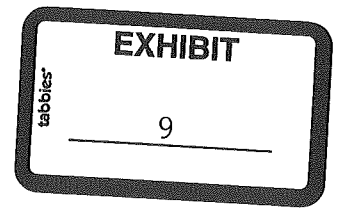
Bode Call & Stroupe, L.L.P.
S. Todd Hemphill, Esquire
Post Office Box 6338
Raleigh, NC 27628-6338

This the 18th day of August, 2011.



Jeff Horton
Chief Operating Officer





North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director
2701 Mail Service Center • Raleigh, North Carolina 27699-2701
<http://www.ncdhhs.gov/dhsr>

Beverly Eaves Perdue, Governor
Lanier M. Cansler, Secretary

Drexdal Pratt, Director
Phone: 919-855-3750
Fax: 919-733-2757

September 27, 2010

CERTIFIED MAIL

William R. Shenton, Esquire
Poyner Spruill LLP
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601

RE: Declaratory Ruling for Wake Radiology Oncology Services, PLLC, Cancer Centers of North Carolina, P.C., US Oncology, Inc., AOR Management Company of Virginia, LLC and WakeMed.

Dear Mr. Shenton:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Drexdal Pratt

DP:JH:peb

Enclosure

cc: Ronald I. Kirschbaum, Esq., Kirschbaum, Nanney, Keenan & Griffin, P.A.
Larry E. Robbins, Esq., Wyrick Robbins Yates & Ponton, LLP
Maureen Demarest Murray, Esq., Smith Moore Leatherwood LLP
Jeff Horton, Chief Operating Officer, DHSR
Craig Smith, Chief, Certificate of Need Section
Steven Lewis, Chief, Construction Section
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section
Medical Facilities Planning Section
Marc Lodge, Special Deputy Attorney General, DOJ



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

IN RE: REQUEST FOR DECLARATORY)	
RULING BY WAKE RADIOLOGY)	
ONCOLOGY SERVICES, PLLC, CANCER)	DECLARATORY RULING
CENTERS OF NORTH CAROLINA, P.C.,)	
US ONCOLOGY, INC., AOR)	
MANAGEMENT COMPANY OF VIRGINIA,)	
LLC AND WAKEMED)	

I, Drexdal Pratt, as Director of the Division of Health Service Regulation, North Carolina Department of Health and Human Services ("Department" or "Agency"), do hereby issue this Declaratory Ruling pursuant to North Carolina General Statute § 150B-4 and 10A NCAC 14A .0103 under the authority granted me by the Secretary of the Department of Health and Human Services.

Wake Radiology Oncology Services, PLLC (hereinafter "WROS"); Cancer Centers of North Carolina, P.C. ("CCNC"); US Oncology, Inc. ("USON") and its subsidiary AOR Management Company of Virginia, LLC ("AOR"); and WakeMed have requested a declaratory ruling to confirm that the acquisition of the membership interests in WROS and the continued operation of the oncology treatment center may proceed without first obtaining a certificate of need. This ruling will be binding upon the Department and the entities requesting it, as long as the material facts stated herein are accurate. This ruling pertains only to the matters referenced herein. Except as provided by N.C.G.S. § 150B-4, the Department expressly reserves the right to make a prospective change in the interpretation of the statutes and regulations at issue in this Declaratory Ruling. Attorneys for the Petitioners have requested this ruling on their behalf and have provided the material facts upon which this ruling is based.

STATEMENT OF THE FACTS

WROS is a North Carolina professional limited liability company presently owned by certain physician-members, each of whom owns a specific percentage of the total membership interests in WROS. WROS provides radiation oncology treatment services at 300 Ashville Avenue, Suite 110, Cary, North Carolina, based on a certificate of need that was issued in 1997 to own an oncology treatment center and to operate a linear accelerator and simulator and other equipment used in furnishing radiation oncology services.

CCNC is a professional corporation organized under the laws of the State of North Carolina. CCNC employs physicians licensed to practice medicine in the State of North Carolina, who provide oncology treatment services, including radiation oncology services through the use of a linear accelerator.

USON is a business corporation organized under the laws of the State of Delaware. Through its subsidiaries, US Oncology provides administrative support for, and furnishes medical equipment used by, oncology practices throughout the United States.

AOR is a limited liability company, a subsidiary of USON and was organized under the laws of the State of Delaware and authorized to do business in North Carolina. AOR provides administrative and other support services to CCNC under a Management Services Agreement with CCNC.

WakeMed is a North Carolina nonprofit corporation engaged in the provision of acute care services and other health care services in Wake County.

WROS established its oncology treatment center on or about July 17, 1998. Since the establishment of its oncology treatment center, WROS has continuously operated the oncology treatment center established pursuant to the CON it received in 1997.

When the CON Law was amended in 2005, WROS already was operating an existing oncology treatment center pursuant to the CON that it had obtained in 1997 and using a linear accelerator and simulator that had been recognized in the SMFP inventory for seven years. Since it already owned the equipment, it was not required to obtain a second CON to be able to continue to operate its linear accelerator and simulator.

Recently, WROS physician owners approved a conversion of WROS from a professional limited liability company to a limited liability company, to occur simultaneously with the sale of ownership interests to CCNC. It is likely that WROS will change its name after the sale. Subsequently, in a separate transaction, WakeMed anticipates purchasing a minority membership interest in the renamed WROS (“the LLC”).

This change in the business form of WROS that has been approved by its physician owners will not constitute a change in or dissolution of WROS, the legal entity that received the CON in 1997 and has continuously operated the oncology treatment center and the linear accelerator and simulator since they became operational.

After these two transactions, the LLC will continue to exist as a legal and business entity, and will continue to own the oncology treatment center and the equipment that was authorized under the 1997 CON, including the linear accelerator and simulator. The oncology treatment center and its equipment will remain at the same location at 300 Ashville Avenue in Cary.

The LLC will not offer any medical services. Oncology treatment services will be furnished by physicians associated with CCNC.

ANALYSIS

The CON law provides that no person shall offer or develop a “new institutional health service” without first obtaining a CON. N.C. Gen. Stat. § 131E-178. The list of new

institutional health services includes “the acquisition by purchase, donation, lease, transfer or comparable arrangement” of a linear accelerator or simulator “by or on behalf of any person,” N.C. Gen. Stat. § 131E-176(16)(f1)5a, 9, and “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,” N.C. Gen. Stat. § 131E-176(16)(b).

Prior declaratory rulings show that the Department has already determined that these definitions do not require an entity to obtain a CON to acquire membership interests in an existing legal entity like WROS which owns and operates a linear accelerator or simulator. The declaratory ruling requested by Petitioners is consistent with the Department’s prior rulings that have interpreted the applicability of the CON Law to the purchase of ownership interests in health care organizations, for the following reasons:

The entity that owns the linear accelerator and simulator will not change, and the same equipment will be used to provide the same radiation oncology services, in the same location. The LLC will continue to own the linear accelerator, the simulator, and all the oncology treatment center assets that were authorized under the 1997 CON and have been used to furnish oncology treatments to patients. Its membership composition initially will change from the present physician members to a single member, CCNC, with the subsequent purchase of a minority interest by WakeMed.

The Proposed Transaction will involve expenditures by CCNC, and later by WakeMed, but these will be purchases of ownership interests in an existing limited liability company that owns the oncology treatment center. There will be no capital expenditure to develop or expand a


health service or health service facility because the same equipment will continue to be operated at the same location, and no expansion of services is proposed.

The Proposed Transaction does not involve the offering or expansion of any new facility, service or equipment, and the state's inventory of linear accelerators and simulators will not change. No new, or additional equipment will be acquired or placed in operation in the State.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the request to be true, I conclude that the Petitioners do not require a certificate of need in order to proceed with the Proposed Transaction.

This the 27th day of September, 2010.



Drexdal Pratt, 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 pre-paid envelope addressed as follows:

CERTIFIED MAIL

William R. Shenton, Esquire
Poyner Spruill LLP
301 Fayetteville Street, Suite 1900
Raleigh, NC 27601
Attorneys for U.S. Oncology, Inc. and AOR Management
Company of Virginia, LLC

Ronald I. Kirschbaum, Esquire
Kirschbaum, Nanney, Keenan & Griffin, P.A.
Post Office Box 19766
Raleigh, NC 27607
Attorneys for Wake Radiology Oncology, PLLC

Larry E. Robbins, Esquire
Wyrick Robbins Yates & Ponton, LLP
Post Office Drawer 17803
Raleigh, NC 27607
Attorneys for Cancer Centers of North Carolina, P.C.

Maureen Demarest Murray, Esquire
Smith Moore Leatherwood LLP
Post Office Box 21927
Greensboro, NC 27420
Attorneys for WakeMed

This the 27th day of September, 2010.



Jeff Horton
Chief Operating Officer



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

IN RE: REQUEST FOR DECLARATORY RULING BY REX HEALTHCARE, INC. AND SMITHFIELD RADIATION ONCOLOGY, LLC))))	DECLARATORY RULING
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I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the “Department”), hereby issue this declaratory ruling to Smithfield Radiation Oncology, LLC (“SRO”) and Rex Healthcare, Inc. (“Rex”) (collectively “Petitioners”) 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. Petitioners have filed a Declaratory Ruling Request (the “Request”) asking the Department to issue a declaratory ruling that Rex may increase its membership interest in SRO to 100% without certificate of need (“CON”) review.

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. Gary S. Qualls of Kennedy Covington Lobdell & Hickman, L.L.P., counsel for Petitioners, has requested this ruling on behalf of Petitioners and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner SRO is a North Carolina limited liability company. Rex currently holds a 25% membership interest in SRO. The remaining members are the physician owners of Triangle Radiation Oncology Services. Petitioners state that Rex will be increasing its membership interest in SRO to 100%, thereby becoming the sole member of SRO.

SRO provides linear accelerator and radiation therapy services. Under prior law, because of the provisions in effect at the time, it was not subject to CON review either as an oncology treatment center or in connection with its acquisition of a linear accelerator.

Petitioners represent that ownership of SRO's linear accelerator will be unaffected by the proposed transaction; it will continue to be owned by SRO. They state that SRO will continue to provide cancer treatment services in materially the same manner as it has done for several years at its existing operational center.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.C.G.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.C.G.S. § 131E-176(16)f1.5a, and (2) "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," N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator by any person because ownership of the linear accelerator here will not change. SRO will continue to be the owner of this equipment, and SRO's legal status as a limited liability company will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that SRO will continue to operate at the same location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Rex of 100% of the membership interest of SRO, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, SRO continues to operate its radiation therapy center at the same location in Smithfield, Johnston County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of SRO with respect to the requirements of the CON law as it relates to SRO. The ruling is limited to the specific facts presented in the Request.

This ____ day of December, 2007.

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:

CERTIFIED MAIL

Gary S. Qualls
Kennedy Covington Lobdell & Hickman, L.L.P.
430 Davis Drive, Suite 400
Morrisville, NC 27560

This _____ day of December, 2007.

Jeff Horton
Chief Operating Officer

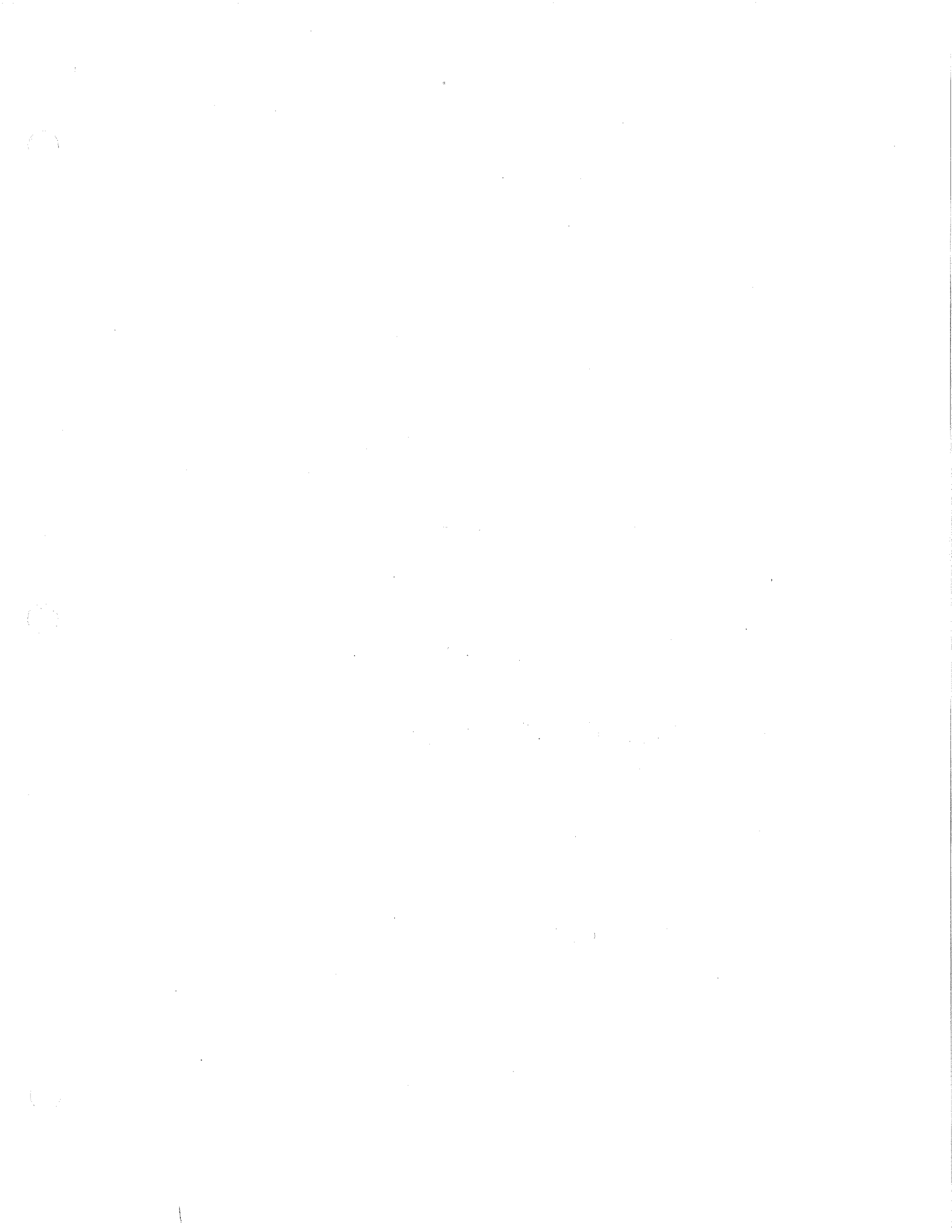




EXHIBIT
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North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

COPY

2701 Mail Service Center • Raleigh, North Carolina 27699-2701

Michael F. Easley, Governor
Dempsey Benton, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3750
Fax: 919-733-2757

September 13, 2007

CERTIFIED MAIL

Susan H. Hargrove, Esquire
Smith, Anderson, Blount, Dorsett
Mitchell & Jernigan, L.L.P.
P.O. Box 2611
Raleigh, NC 27602-2611

RE: Declaratory Ruling for Radiation Therapy Services, Inc. and North Carolina Radiation Therapy Management Services, Inc.

Dear Ms. Hargrove:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,

Robert J. Fitzgerald

RJF:JH:peb

Enclosure

- cc: Jeff Horton, Chief Operating Officer, DHSR
- Lee Hoffman, Chief, Certificate of Need Section, DHSR
- Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR
- Marc Lodge, Special Deputy Attorney General, DOJ



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

COPY

IN RE: REQUEST FOR)
DECLARATORY RULING BY RADIATION)
THERAPY SERVICES, INC. AND NORTH) DECLARATORY RULING
CAROLINA RADIATION THERAPY)
MANAGEMENT SERVICES, INC.)

I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to Radiation Therapy Services, Inc. d/b/a/ 21st Century Oncology ("RTS") and North Carolina Radiation Therapy Management Services, Inc. ("NC Radiation") (collectively "Petitioners") 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. Petitioners have filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that they may acquire all of the stock of Carolina Radiation and Cancer Treatment Center, Inc. ("CRTC") without certificate of need ("CON") review.

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. Susan H. Hargrove, Sean A. Timmons, and Jennifer B. Markhan of Smith, Anderson, Blount, Dorsett, Mitchell & Jernigan, L.L.P., counsel for Petitioners, have requested this ruling on behalf of Petitioners and have provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for Petitioners are set out below.

STATEMENT OF THE FACTS

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Except as noted, the following statement of the facts is based on the representations of Petitioners in the Request.

Petitioner RTS is a Florida corporation. NC Radiation is a North Carolina corporation that is a wholly-owned subsidiary of RTS. Both have their principal business address in Fort Myers, Florida.

Petitioners wish to acquire 100% of the issued and outstanding stock of CRTC, which they state is a North Carolina corporation owned by Dr. Gordon Koltis that operates a radiation therapy facility for cancer patients. Petitioners describe CRTC as an oncology treatment center that, prior to 26 August 2005, would have been a "health service facility" as defined in N.C.G.S. § 131E-176(9b). S.L. 2005-325 eliminated oncology treatment centers from the category of "health service facilities," effective 26 August 2005.

Petitioners also state that CRTC "owns and operates two linear accelerators" and "one simulator." Request, p. 3. Footnote 1 to the Request states:

CRTC has represented to Petitioners that it entered into binding obligations to acquire the second linear accelerator prior to August 26, 2005, and that the acquisition of the second linear accelerator cost less than \$750,000, including the cost of the equipment, studies, surveys, designs, plans, working drawings, specifications, construction, installation, and other activities essential to acquiring and making operational the second linear accelerator.

I note from the files of the Department that the inventory report of linear accelerator equipment submitted by Carolina Radiation Medicine, P.A., certified and dated by Gordon G. Koltis on April 6, 2007, identifies only one linear accelerator owned by CRTC. The Department files do not contain any information concerning the purported second linear accelerator.

Petitioners represent that they have executed a stock purchase agreement by which NC Radiation will acquire 100% of the issued and outstanding capital stock of CRTC from Dr. Koltis. After closing the transaction, Petitioners state that CRTC will remain a separate corporate entity that is a wholly-owned subsidiary of NC Radiation. They state that CRTC will continue to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways. Petitioners will pay more than two million dollars to purchase the CRTC stock. The closing of the transaction is conditioned on receiving confirmation from the Department that acquisition of the stock will not require a certificate of need.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new institutional health service" to include: (1) "The acquisition by purchase, donation, lease, transfer, or comparable arrangement" of a linear accelerator "by or on behalf of any person," N.G.C.S. § 131E-176(16)f1.5a, and (2) "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," N.C.G.S. § 131E-176(16)b.

The transaction described by Petitioners does not constitute the acquisition of a linear accelerator or a simulator by any person because ownership of the one reported linear accelerator and one reported simulator here will not change. CRTC will continue to be the owner of these two pieces of equipment, and CRTC's legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or a health service facility, since Petitioners represent that CRTC will continue to operate at the same

location in a manner that is the same in all material respects as it operated prior to the transaction. In addition, pursuant to S.L. 2005-325, oncology treatment centers are not "health service facilities" for purposes of the CON law.

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Finally, on the specific facts of this case, the transaction proposed by Petitioners is not "a capital expenditure . . . which relates to the provision of a health service" within the meaning of N.C.G.S. § 131E-176(16)b. The definition of "health service" specifically "does not include administrative and other activities that are not integral to clinical management." Petitioners' representations indicate that stock ownership of CRTC is not integral to the clinical management of CRTC, because in all material respects the operations of CRTC will not change.

I specifically except from this Ruling any conclusions as to the status or legality of the ownership of a purported second linear accelerator by CRTC. The Department has no notice of the existence or ownership of the second linear accelerator, and I make no finding that CRTC may acquire or operate, or has properly acquired and operated, a second linear accelerator without CON review.

CONCLUSION

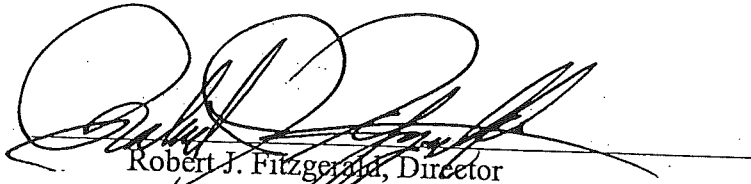
For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by Petitioners of 100% of the outstanding and issued stock of CRTC, in the manner represented by Petitioners in the Request, is not subject to CON review.

This ruling is subject to the condition that, after the transaction, CRTC continues to operate its freestanding radiation therapy facility at the same location in Greenville, Pitt County, North Carolina, in the same manner in which it operated prior to the transaction in all material ways.

This ruling is not intended to address, expand or validate any activities or status of CRTCC with respect to the requirements of the CON law as it relates to CRTCC. The ruling is limited to the specific facts presented in the Request. It specifically does not address the status of any linear accelerator that CRTCC may own or claim to own.

COPY

This 14th day of September 2007.


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

CERTIFICATE OF SERVICE


COPY

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 pre-paid envelope addressed as follows:

CERTIFIED MAIL

Susan H. Hargrove, Esq.
Smith, Anderson, Blount, Dorsett
Mitchell & Jernigan, L.L.P.
P.O. Box 2611
Raleigh, NC 27602-2611

This the 14th day of September, 2007.



Jeff Horton
Chief Operating Officer

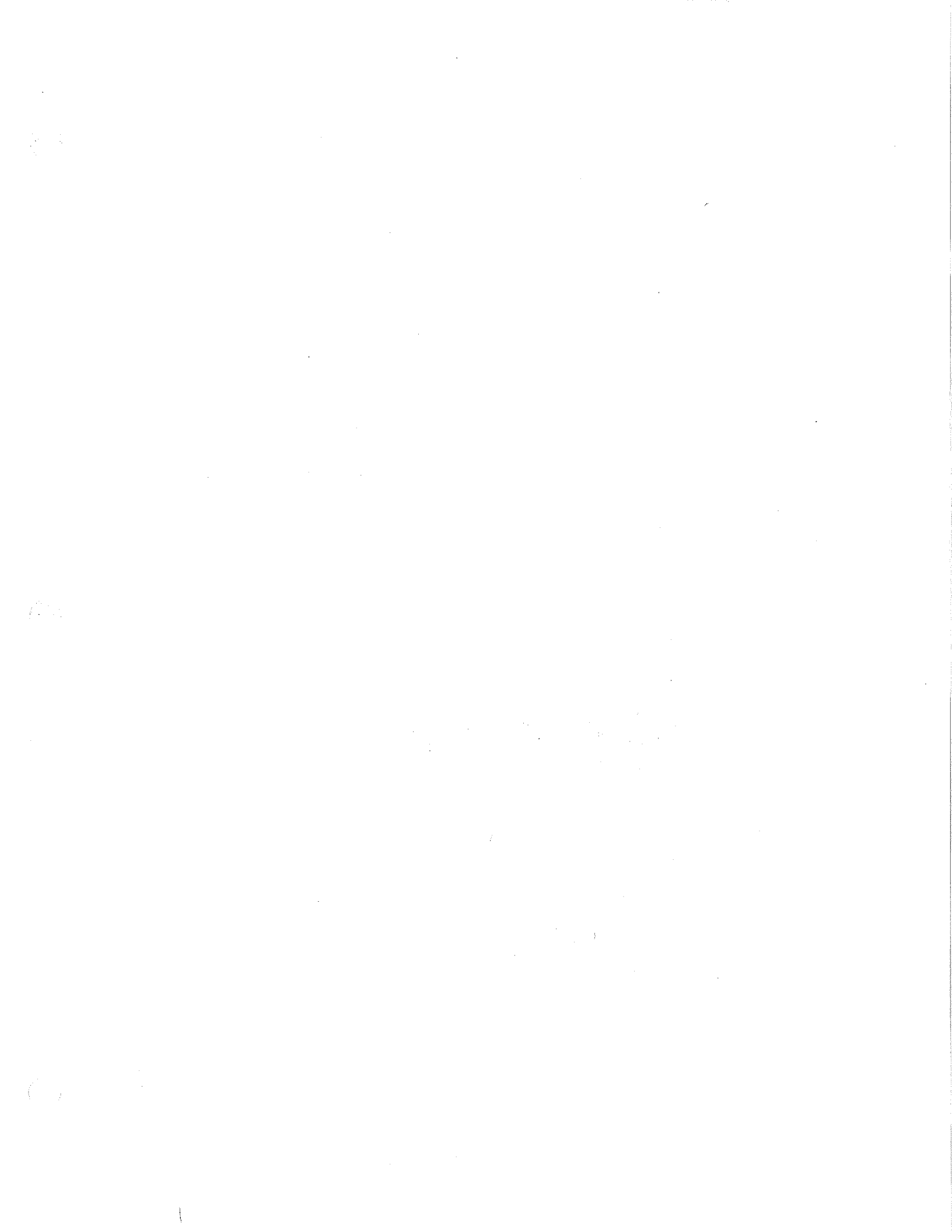




EXHIBIT
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COPY

North Carolina Department of Health and Human Services
Division of Health Service Regulation
Office of the Director

2701 Mail Service Center • Raleigh, North Carolina 27699-2701

Michael F. Easley, Governor
Dempsey Benton, Secretary

Robert J. Fitzgerald, Director
Phone: 919-855-3750
Fax: 919-733-2757

January 24, 2008

CERTIFIED MAIL

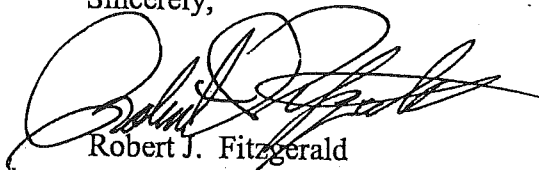
Terrill Johnson Harris, Esquire
Smith Moore, LLP
P.O. Box 21927
Greensboro, NC 27420

RE: Declaratory Ruling for the New Hanover Perfusionists, Inc.

Dear Mr. Harris:

I am enclosing a Declaratory Ruling that you requested. If questions arise, do not hesitate to let me know.

Sincerely,



Robert J. Fitzgerald

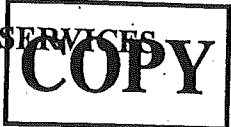
RJF:JH:peb

Enclosure

cc: Jeff Horton, Chief Operating Officer, DHSR
Azzie Conley, Chief, Acute and Home Care Licensure and Certification Section, DHSR
Marc Lodge, Special Deputy Attorney General, DOJ



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



IN RE: REQUEST FOR DECLARATORY)
 RULING BY NEW HANOVER)
 PERFUSIONISTS, INC.) DECLARATORY RULING

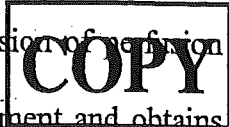
I, Robert J. Fitzgerald, Director of the Division of Health Service Regulation (the "Department"), hereby issue this declaratory ruling to New Hanover Perfusionists, Inc. ("NHP") pursuant to N.C.G.S. § 150B-4, 10A NCAC 14A.0103, and the authority delegated to me by the Secretary of the North Carolina Department of Health and Human Services. NHP has filed a Declaratory Ruling Request (the "Request") asking the Department to issue a declaratory ruling that it may acquire all of the stock of Coastal Perfusion Services, Inc. ("Coastal") without certificate of need ("CON") review.

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. Terrill Johnson Harris of Smith Moore LLP requested this ruling on behalf of NHP and has provided the statement of facts upon which this ruling is based. The material facts as provided by counsel for NHP are set out below.

STATEMENT OF THE FACTS

NHP states that it is a North Carolina corporation with its principal place of business in Wilmington, North Carolina. NHP provides perfusion services to New Hanover Regional Medical Center ("New Hanover Regional") pursuant to a perfusion services contract. The actual heart-lung bypass equipment is owned by Coastal and by Wilmington Perfusion Company

("Wilmington"). NHP contracts with Coastal and Wilmington for the provision of perfusion services. New Hanover Regional does not own any heart-lung bypass equipment and obtains perfusion services exclusively through NHP.



Coastal is a North Carolina corporation with its principal place of business in Wilmington, North Carolina. Its sole shareholder is Charles Hunter, M.D. ("Dr. Hunter"). Dr. Hunter is a cardiothoracic surgeon who has retired from the active practice of medicine.

Wilmington Perfusion Company is a North Carolina corporation with its principal place of business in Wilmington, North Carolina. Its sole shareholder is Howard F. Marks, M.D. ("Dr. Marks"), a cardiothoracic surgeon. Both Dr. Hunter and Dr. Marks are currently shareholders in NHP.

Dr. Hunter has agreed to sell his interest in Coastal to NHP because he has retired from the active practice of medicine and no longer wishes to be involved in perfusion services. NHP plans to acquire 100 percent of the issued and outstanding stock of Coastal.

After closing the stock sale transaction, NHP represents that Coastal will remain a separate corporate entity that is a wholly-owned subsidiary of NHP. NHP will own the stock instead of Dr. Hunter, but all else will remain the same. Coastal will continue to operate the heart-lung bypass equipment at New Hanover Regional pursuant to an agreement with NHP, which in turn has a perfusion services agreement with New Hanover Regional. The manner in which the equipment is operated and the services will not change in any respect after the proposed transaction is closed.

ANALYSIS

N.C.G.S. § 131E-178 provides that no person shall offer or develop "a new institutional health service" without first obtaining a CON. N.G.C.S. § 131E-176(16) defines "new

institutional health service” to include: (1) “The acquisition by purchase, donation, lease, transfer, or comparable arrangement” of a heart-lung bypass machine “by or **COPY** on behalf of any person,” N.G.C.S. § 131E-176(16)f1.5, and (2) “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,” N.C.G.S. § 131E-176(16)b.

The transaction described by NHP does not constitute the acquisition of a heart-lung bypass machine by any person because ownership of the heart-lung bypass machine here will not change. Coastal will continue to be the owner of this equipment, and Coastal’s legal status as a corporate entity will not change.

Similarly, the transaction is not an obligation to develop or expand a health service or health service facility, since NHP represents that Coastal will continue to operate at the same location in a manner that is the same in all material respects as it operated prior to the transaction. Coastal is not within the definition of a health service facility. N.C.G.S. § 131E-176(9b).

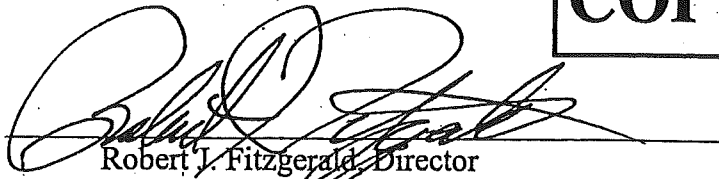
CONCLUSION

For the foregoing reasons, assuming the statements of fact in the Request to be true, I conclude that the acquisition by NHP of 100% of the outstanding and issued stock of Coastal, in the manner represented by NHP in the Request, is not subject to CON review.

This ruling does not address any licensure issues, and NHP shall continue to be responsible for providing all required licensure information to the Acute and Home Care Licensure Section of the Department.

This 24th day of January, 2008.

COPY



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

CERTIFICATE OF SERVICE

COPY

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 pre-paid envelope addressed as follows:

CERTIFIED MAIL

Terrill Johnson Harris
Smith Moore, LLP
P.O. Box 21927
Greensboro, NC 27420

This the 24th day of January, 2008.

Patricia Bagent for

Jeff Horton
Chief Operating Officer